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No. 08-624

IN THE
Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S,
Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a form of declaratory judgment called a "civil action to obtain patent certainty," 21 U.S.C. § 355(j)(5)(C), premised on an underlying cause of action for patent infringement, remains justiciable under Article III of the Constitution after the pioneering drug company defendant holding the patent irrevocably covenants not to sue the generic drug company plaintiff for infringement of the patent at issue.

2. Whether the causation necessary to support constitutional standing exists where the claimed injury in fact traces to a patent holder's compliance with a mandatory patent listing obligation imposed by a federal statute and backed by criminal sanction.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioners hereby state that:

(1) Forest Laboratories, Inc. does not have a parent corporation, and no publicly held corporation owns 10% or more of Forest Laboratories, Inc.'s stock.

(2) Forest Laboratories Holdings, Ltd. is a wholly owned subsidiary of Forest Laboratories, Inc. Forest Laboratories, Inc. is the only publicly held corporation that owns 10% or more of Forest Laboratories Holdings, Ltd.'s stock.

(3) H. Lundbeck A/S does not have a parent corporation and no publicly held corporation owns 10% or more of H. Lundbeck A/S's stock.

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INTRODUCTION

In a case of extreme significance to the entire pharmaceutical industry, a divided panel of the Federal Circuit has interpreted the Hatch-Waxman Act[1] in a manner that upsets the careful balance Congress established in that landmark statute as between providing incentives for pioneering companies—such as Petitioner Forest (collectively Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S)—and encouraging the entry of generic enterprises—such as Respondent Caraco Pharmaceutical. In doing so, the panel has upset settled law and tugged at foundational principles of judicial power under Article III of the Constitution. Sweepingly interpreting this Court's decision two Terms ago in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), the divided panel—over a sharp dissent by Judge Daniel Friedman—did great violence to the congressionally ordained structure erected almost a generation ago by Hatch-Waxman. This will usher in an era of destabilizing and counterproductive patent litigation. Review is warranted now.

The Hatch-Waxman Act stands at the interface of the patent statutes and the approval process for pioneer and generic drugs under the food and drug laws. Notwithstanding its profound importance to the whole of the pharmaceutical industry, Hatch-

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[1] This is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

Waxman has been considered by this Court only twice in the statute's 24-year lifespan.[2] Even with those two decisions, however, never before has this Court addressed a question arising under the core provisions of the Hatch-Waxman Act, let alone such a case presenting grave concerns under Article III of the Constitution.

Contrary to a large body of law holding that covenants not to sue moot suits premised on the relevant cause of action to which the covenant relates, a divided Federal Circuit panel held in this case that a new type of declaratory judgment suit created by Hatch-Waxman changed the previously clear Article III consequences of such covenants. To our knowledge, never before has a court stripped a class of litigants of their pre-existing right to avoid suit by granting an enforceable covenant not to sue—thereby functionally conscripting them as unwilling litigants—especially in the absence of a clear directive from Congress to do so.

The Federal Circuit thought its result was supported by this Court's decision two terms ago in *MedImmune*. But *MedImmune* did not involve Hatch-Waxman or its newly devised declaratory judgment suits designed to probe the boundaries of Article III. *See* 35 U.S.C. § 271(e)(5) (authorizing unique form of declaratory judgment action "to the

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[2] *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (holding preclinical studies fell within the Section 271(e)(1) exception to patent infringement for uses reasonably related to developing and submitting information to the FDA for purposes of that agency's regulation of drugs); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (considering whether this drug-based exception also applied to medical devices).

extent consistent with the Constitution"). To the contrary, *MedImmune* held only that a patent licensee could pay royalties under protest without mooting its right to bring a declaratory judgment action to determine whether the licensed patent was valid and not infringed. Nothing in that decision speaks to whether Hatch-Waxman declaratory judgment actions remain justiciable means to resolve a dispute about infringement after the patent holder grants a covenant not to sue.

For decades, the lower courts and the Food and Drug Administration ("FDA") have been grappling with the complexities Hatch-Waxman creates for patent litigation. That this Court's intervention is needed to clarify the operation of Hatch-Waxman—and the application of Article III to its regime—is loudly testified to by the invalidation of numerous Hatch-Waxman FDA regulations and interpretations leading up to the adoption of Hatch-Waxman Act-specific declaratory judgment suits.[3]

In one of the cases invalidating an FDA regulation, the D.C. Circuit suggested that declaratory judgment suits might smooth the rough edges of Hatch-Waxman. Surveying the potential pitfalls of such a purported solution, however, the court recognized:

> [Generic drug company] Mylan has also noted what may be a more serious fly in the

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[3] *See, e.g., Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (invalidating FDA's "successful defense" Hatch-Waxman regulation); *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 42, 47 (D.D.C. 2000) (invalidating a different FDA Hatch-Waxman regulation construing the statutory phrase "a decision of a court").

> (patented) ointment. In order to satisfy the Constitution's case or controversy requirement, a party filing a declaratory judgment action must show that there is a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Mova, 140 F.3d at 1073 (internal quotation marks omitted).

Notwithstanding such a cautionary note, Congress decided to adopt precisely such a declaratory judgment solution in 2003 to the problems emergent in the Hatch-Waxman regime. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007) (discussing Congress's creation of the so-called "civil action to obtain patent certainty").

The *Mova* court actually saw two related "flies in the ointment" for expanded use of declaratory judgments under Hatch-Waxman: (1) the Federal Circuit's "reasonable apprehension of suit" limitation on when declaratory relief is viable in patent suits; and (2) the Article III requirement of a "Case or Controversy." *MedImmune* eliminated the former as an obstacle. 127 S. Ct. at 774 n.11. But *MedImmune* did not address, much less resolve, the entirely distinct question of the limits of Hatch-Waxman declaratory judgment actions as cabined by Article III.

Accordingly, there is an urgent need for this Court to authoritatively construe the Hatch-Waxman form of declaratory judgment action and resolve the constitutional question *MedImmune* did not resolve. This case should be chosen as the

vehicle because of its exceptional importance to the business community. At the *en banc* stage, representatives of all of the major interests regulated or touched by Hatch-Waxman asked the Federal Circuit to reconsider its erroneous decision: pioneer drug companies, a leading generic drug company, as well as pharmaceutical and biotechnical trade associations. Urging rehearing, this broad coalition of shared interests argued vigorously that the divided panel's decision radically rebalanced congressionally designed incentives to innovation and for the introduction of generic competition, while expanding the uses of Hatch-Waxman declaratory judgment suits beyond the bounds of the Constitution and of congressional intent. Indeed, one of Caraco's generic competitors was alarmed that the Federal Circuit's decision robs generic companies of the benefits Congress intended to confer on the first generic companies to challenge pioneer patents. Left unchecked, the decision will trigger a new wave of litigation the drafters of Hatch-Waxman did not remotely intend.

OPINIONS BELOW

The Federal Circuit's decision is reported at 527 F.3d 1278 (Fed. Cir. 2008) and reprinted in the Appendix ("App.") at 1a. The order of the United States District Court for the Eastern District of Michigan dismissing for lack of subject matter jurisdiction is reprinted at App. 47a.

JURISDICTION

The court of appeals rendered its decision on

April 1, 2008, and denied a timely petition for rehearing and rehearing en banc on June 24, 2008.[4] App. 45a. On September 12, 2008, Chief Justice Roberts extended the time for filing this petition to and including November 6, 2008. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

Article III, Section 2, Clause 1 of the Constitution provides in relevant part that "[t]he judicial Power shall extend to all Cases, in Law and Equity [and] Controversies . . . ." Pursuant to Court Rule 14.1(f), pertinent statutory provisions are reprinted in the Appendix at 106a-110a.

STATEMENT OF THE CASE

A. STATUTORY BACKGROUND

1. The Hatch-Waxman Act governs the approval of all drugs introduced into interstate commerce. 21 U.S.C. § 355(a). Under the Act, a pioneer drug company must obtain approval from the FDA for a new drug by submitting a New Drug Application ("NDA"). Pioneer applicants are required to file with the FDA the patent number and expiration date of all patents that claim the drug or claim a method of using the drug, if a claim of patent infringement could reasonably be asserted were the drug to be manufactured, used, or sold by another. 21 U.S.C. § 355(b)(1). The FDA is then assigned a ministerial duty to list these patents in a publication commonly

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[4] The court of appeals granted a 14-day extension of time in which to file a petition for rehearing and rehearing en banc.

known as the "Orange Book." Drugs approved by the FDA are referred to as "listed drugs." 21 U.S.C. § 355(j)(2)(A)(i). The patents listed in the Orange Book for each listed drug are referred to as "listed patents." *See* 21 C.F.R. § 314.53(f).

Failure to submit the patent information is a ground for denying NDA approval. 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v) (1999); 21 C.F.R. § 314.53(b),(c) (2004). Indeed, failure to provide an accurate and complete submission of patent information subjects the holder to potential criminal liability. 21 C.F.R. § 314.53(c)(2)(i)(Q) (2004).

2. The Hatch-Waxman Act streamlines approval for generic versions of listed drugs by allowing generic drug manufacturers to submit an "Abbreviated New Drug Application" ("ANDA"). 21 U.S.C. § 355(j). If an ANDA applicant desires approval to market a generic version of the listed drug prior to expiration of a patent covering the listed drug, the ANDA applicant must include a certification that the patent covering the listed drug is invalid or not infringed by the drug that is the subject of the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is known as a "Paragraph IV" certification. Submission of a Paragraph IV certification constitutes an "artificial" act of infringement. 35 U.S.C. § 271(e)(2); *Eli Lilly*, 496 U.S. at 676.

The first applicant to submit an ANDA for a listed drug that includes a Paragraph IV certification against a listed patent is eligible to receive 180 days of exclusive generic marketing. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). "We will call this Edenic moment of freedom from the pressures of the

marketplace the statute's 'exclusivity period.'" *Mova*, 140 F.3d at 1064-65. The FDA may not approve any subsequent ANDA until after this 180-day exclusivity period has expired. The purpose of the exclusivity period is to incentivize generic drug companies to take on the economic and litigation risks inherent in challenging pioneer patents. *Id.* at 1075. The exclusivity period begins to run (1) when the first Paragraph IV ANDA filer commercially markets its drug (the commercial marketing trigger), or (2) on the date of a court decision holding the patent that was the subject of the certification to be invalid or not infringed (the court-judgment trigger). 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

3. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernizaton Act of 2003 ("Medicare Modernization Act"). *See supra* n.1. The Medicare Modernization Act amended the Hatch-Waxman Act by adding a new provision for a "civil action to obtain patent certainty" (hereafter "CAPC"). 21 U.S.C. § 355(j)(5)(C). Under this provision, if the holder of the NDA for a listed drug does not bring an infringement action within 45 days of receiving notice of a Paragraph IV certification for that drug, the ANDA applicant may bring a civil action for a declaratory judgment that the patents at issue are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C)(i).[5]

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[5] The Medicare Modernization Act also revised the framework under which the first Paragraph IV filer can forfeit its exclusivity period if it does not market a drug within specified periods of time. 117 Stat. at 2457-60, Section 1102. These forfeiture provisions, however, do not apply to ANDAs (such as the ANDA relevant to this case) containing Paragraph IV

The Medicare Modernization Act provides that federal courts have subject matter jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The purpose of this expression of intent was to test the boundaries of this new form of declaratory judgment against Article III. *See* App. 10a-11a (relying on statement of Senator Kennedy).

B. FACTUAL BACKGROUND

1. Forest markets the blockbuster drug Lexapro® ("Lexapro"), which is used to treat depression and generalized anxiety disorder. As part of the mandatory process for avoiding penalties and obtaining FDA approval for Lexapro, Forest filed the necessary information concerning two patents with the FDA: U.S. Patent No. Re. 34,712 (the '712 patent) and U.S. Patent No. 6,916,941 (the '941 patent).

Ivax Pharmaceuticals, Inc. ("Ivax") was the first ANDA applicant to file a Paragraph IV certification for the '712 and '941 patents. App. 12a. Ivax is therefore eligible for up to 180 days of generic market exclusivity for each patent, which will begin to run on the earlier of (1) the day Ivax begins marketing its generic drug or (2) the day a court determines that, for each such patent at issue, the patent is invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

In response to Ivax's Paragraph IV certification,

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certifications that were filed before December 8, 2003. 117 Stat. at 2460, Section 1102(b).

which represents an act of infringement under 35 U.S.C. § 271(e)(2), Forest sued Ivax for infringement of the '712 patent. Ivax counterclaimed that the '712 patent was invalid and unenforceable. Forest prevailed completely in that litigation, obtaining a judgment that the '712 patent was valid and enforceable, along with a stipulation that Ivax's ANDA infringed that patent. App. 12a-13a. This judgment was affirmed in its entirety on appeal. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

2. In May 2006, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed ANDA 78-219 for Lexapro with the FDA. This ANDA included a Paragraph IV certification for the '712 and '941 patents. App. 15a-16a. Caraco's was the third Paragraph IV certification on the '712 patent and the seventh Paragraph IV certification on the '941 patent. In response to ANDA 78-219, Forest sued Caraco for infringement of the '712 patent (but not the '941 patent). App. 16a. That litigation is ongoing.

When Forest did not sue Caraco for infringement of the '941 patent, Caraco filed a separate action seeking a declaration that its ANDA did not infringe the '941 patent. App. 16a, 83a. Caraco did not contest the validity of the '941 patent. *Id.*

Forest then moved to dismiss Caraco's declaratory judgment action for lack of jurisdiction. App. 17a. Forest later granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent to confirm that no case or controversy existed between Forest and Caraco. The covenant provided as follows:

> [Forest] hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use sale, or offer for sale or importation of the generic products described by ANDA 78-219.

App. 19a-20a; 103a-104a.

C. PROCEEDINGS BELOW

On May 31, 2007, the district court granted Forest's motion to dismiss. App. 47a. Ruling from the bench, the court explained that because Forest had granted Caraco a covenant not to sue, Caraco suffered *no risk* of being sued for infringement and its complaint was "asking for the same relief as they already have." Hence, a controversy no longer existed under Article III, App. 77a-78a, and Caraco could not be found liable for infringement.

A divided panel of the Federal Circuit reversed. The majority held that, despite the covenant not to sue, "Caraco's declaratory judgment action presents a continuing Article III controversy" because, "in the context of the Hatch-Waxman framework, Forest's covenant not to sue did not eliminate the controversy between the parties." App. 2a.

Addressing the three constitutional requirements for standing, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998), the Federal Circuit *first* concluded that there was an injury-in-fact because Caraco was being excluded from the drug market by the '941 patent. App. 24a-25a. Specifically, because Ivax was the first ANDA-filer

with respect to Lexapro, Caraco could not enter the market for generic Lexapro until Ivax's 180-day exclusivity period had expired. App. 26a-27a. A subsequent Paragraph IV ANDA filer such as Caraco can trigger Ivax's exclusivity period only by obtaining a judgment that the '941 patent is either invalid or not infringed. App. 27a-28a.

Second, the Federal Circuit concluded that Caraco's injury is traceable to Forest. The court stated that "Forest's listing of the '712 and '941 patents in the Orange Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both patents are invalid or not infringed by its generic drug." App. 27a. The court concluded that Forest's listing, rather than the Hatch-Waxman Act, caused Caraco's injury by preventing Caraco from entering the marketplace. *Id.*

Third, the Federal Circuit concluded that Caraco's injury is redressable by a declaratory judgment that the '941 patent is not infringed. App. 27a-28a. According to the court of appeals, "[i]f Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible." App. 28a.[6] The Federal Circuit emphasized that its

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[6] The dissenting judge took issue with that claim (see below). In addition, on September 2, 2008, after the decision here issued, a new patent issued for Lexapro—U.S. Patent No. 7,420,069 ("'069 patent"). The issuance of this new patent underscores both that Caraco is *not* close to market entry, and

reading of the purposes of the CAPC declaratory action created by Congress in 2003 was consistent with the "remarks of Senator Kennedy." App. 30a.

Addressing the other two justiciability doctrines, the Federal Circuit concluded that Caraco's declaratory judgment claim was ripe and not moot. App. 31a-36a. Although the court below conceded that Forest's covenant "would moot Caraco's case" if a threat of an infringement lawsuit "was the *only action* allegedly taken by Forest that effectively excluded Caraco from the marketplace," App. 34a (emphasis added), the panel nevertheless concluded that the covenant did not moot this case because "Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context." App. 35a.

Judge Friedman dissented. Although agreeing that Caraco's declaratory judgment claim "stems from and is based upon particular provisions of the Hatch-Waxman Act," not from any danger of damages for infringement, App. 38a, Judge Friedman maintained that Caraco's declaratory judgment claim was unripe because it was based on contingencies that may never come to pass (such as a victory by Caraco in pending patent litigation with Forest over the '712 patent). App. 40a-41a.

Judge Friedman further opined that the

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that the Federal Circuit mistakenly believed that the exclusive source of Caraco's market exclusion is Forest's purportedly discretionary decision to list the '941 patent in the Orange Book. Notably, Caraco has also failed to file a Paragraph IV certification on the '069 patent (listed September 23, 2008), though Forest has already received nine such certifications from other generic companies.

majority's "theory" was inconsistent with Congress's policy judgment to favor the *first* ANDA filer. App. 40a. In the absence of an "indication that [Senator Kennedy's] statements reflected the views of the majority of the committee or of the Senate, or the sponsors of" the Medicare Modernization Act in 2003, the dissenting judge was unwilling to conclude that such statements were an "adequate basis for determining the scope and meaning of this legislation." App. 41a. Judge Friedman also pointed out that the majority was glossing over Senator Kennedy's express caveat: "We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue . . . ." App. 42a.

Overall, in light of Forest's covenant not to sue, Judge Friedman would have held that, "'under all the circumstances,'" there was not a "'substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment.'" App. 41a. (quoting *MedImmune*, 127 S. Ct. at 771).

Forest sought *en banc* review or panel rehearing. Numerous amicus briefs were filed in support of rehearing.[7] Although it called for a response, the Federal Circuit ultimately denied the petition.

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[7] In addition to support by Ivax, the generic first ANDA filer, Forest had the support of pioneer drug companies Merck & Co., Inc. and Pfizer, Inc., industry trade associations the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization, and the public interest organization, the Washington Legal Foundation.

REASONS FOR GRANTING THE WRIT

The Federal Circuit's exclusive appellate jurisdiction over patent disputes, 28 U.S.C. § 1295(a)(1), (a)(4), precludes the emergence of a split among the Circuits on the questions presented. *Compare* S. Ct. R. 10(a). Nevertheless, the path by which the Federal Circuit reached its conclusion ran roughshod over decisions of this Court, while feeding circuit splits and intra-circuit divisions within the Federal Circuit itself.

Despite conceding that a viable infringement action was terminated by virtue of the covenant not to sue, *see* App. 34a, the Federal Circuit's conceptual framework required it to recast the familiar cause of action for patent infringement as a cause of action Congress has never seen fit to create. App. 35a-36a. Hatch-Waxman's operation is thus seriously distorted. Additionally, this judicial legerdemain ignores the bedrock constitutional requirement that a valid injury in fact sufficient to support standing exists only where such injury results from invasion of a "legally protected interest." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). And a "legally protected interest" here is nothing other than a congressionally created cause of action. Since at least one other Circuit has also recently announced, in derogation of *Lujan*, that the legal protectability requirement confuses standing with the merits, this Court should intervene to clarify that *Lujan* applies equally to complex regulatory regimes like Hatch-Waxman. There is no standing to press claims for redress for an injury based on a nonexistent cause of action.

The Federal Circuit decision also violated this

Court's case law by cavalierly tracing causation to actions by third parties not before the court. Here, the court of appeals held that Forest's decision to list its '941 patent in the Orange Book caused Caraco's injury. But Forest's action was mandatory, not discretionary. It is not Forest's purported listing decision (in reality a listing *obligation*) that prevented Caraco from freely entering the relevant drug market. Instead, it was Congress's decision to exclude Caraco from the market for the purpose of favoring the first ANDA filer (here Ivax) that is the cause of Caraco's claimed injury.

Other Circuits have found that no standing exists when causation for an alleged injury traces to sovereign legal action, rather than to discretionary private action. The Federal Circuit's decision in this case conflicts with those rulings.

This petition should be granted for the further reason that the decision below threatens to subvert Article III and to destabilize the careful balance Congress struck among the rights of pioneer drug companies, ANDA first filers, and subsequent ANDA filers. In its quest to serve the laudable goal of speeding the introduction of generic drugs into the market, the Federal Circuit lost sight of the stopping points in the Hatch-Waxman regime and the law of justiciability. Together, those intertwined requirements serve to protect the substantial investments in innovation pioneer companies incur, as well as the large risks ANDA first filers accept when they attempt to prove a listed patent is either invalid or not infringed.

I. CONTRARY TO SUPREME COURT AND CIRCUIT DECISIONAL LAW, THE FEDERAL CIRCUIT'S DECISION FINDS STANDING WHERE NO "LEGALLY PROTECTED INTEREST" IS AT STAKE.

1. This Court has repeatedly held that not every injury is sufficient to create a constitutional case or controversy. *See, e.g., Raines v. Byrd*, 521 U.S. 811, 825-26 (1997); *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 485-86 (1982). To the contrary, an injury must be actionable in order to give rise to constitutionally cognizable injury. This is a corollary of the point that not every "case" or "controversy" can give rise to Article III jurisdiction. Instead, "the Constitution's central mechanism of separation of powers depends largely upon common understanding of what activities are appropriate to legislatures, to executives, and to courts." *Lujan*, 504 U.S. at 559-60.

Consider *McConnell v. FEC*, 540 U.S. 93 (2003). In that case, certain plaintiffs challenged a particular provision of the Bipartisan Campaign Finance Reform Act that relaxed prior limits on "hard money" contributions. That particular subgroup of plaintiffs argued that this statutory expansion of contribution limits injured them by reducing their ability to participate in elections on an equal footing based merely on their economic status. The majority held that the plaintiffs lacked standing because the ability to compete in an election only so long as all participants have equal resources is not a "legally cognizable right." *Id.* at 227. *See also Warth v. Seldin*, 422 U.S. 490, 500 (1975) (standing "often turns on the nature and

source of the claim asserted.").

The lower courts have largely followed the instruction of this Court to test assertions of injury for standing purposes to determine if they are premised upon a valid cause of action. Take, for instance, the Fourth Circuit's opinion in *Salt Institute v. Leavitt*, 440 F.3d 156 (4th Cir. 2006). *Salt Institute* held that since the Information Quality Act created no private right of action and there was no common law cause of action to correct false information, the absence of any legally cognizable cause of action required the suit to be dismissed for want of standing. *Id.* at 158-59.[8]

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[8] *See also Pichler v. UNITE*, 542 F.3d 380, 390-92 (3d Cir. 2008) (following *Lujan*); *Neese v. Johanns*, 518 F.3d 215, 219 (4th Cir. 2008) (same); *AT&T Mobility, LLC v. National Ass'n for Stock Car Auto Racing, Inc.*, 494 F.3d 1356, 1360-62 (11th Cir. 2007) (same); *Morlan v. Universal Guar. Life Ins. Co.*, 298 F.3d 609, 621 (7th Cir. 2002) (Posner, J.) ("The possession of a legally protectable interest is a prerequisite to suing because otherwise the possessor of that interest would find himself unable to enforce it if another person, an officious intermeddler, had brought suit to enforce it (like a bounty hunter) first."); *Potthoff v. Morin*, 245 F.3d 710, 717-18 (8th Cir. 2001) ("an abstract constitutional right is not justiciable unless a legally protectible interest is at stake"); *Claybrook v. Slater*, 111 F.3d 904, 906-07, 909 (D.C. Cir. 1997) (following *Lujan*); *Alliance Against IFQs v. Brown*, 84 F.3d 343, 351-52 (9th Cir. 1996) (rejecting particular cause of action under the Magnuson Act where the fishermen's claimed injury was based on an interest belonging to the State of Alaska and thus not "an invasion of a legally protected interest . . . of the [plaintiffs]."") (internal quotation omitted); *In re Joint E. & S. Dist. Asbestos Litig.*, 78 F.3d 764, 780 (2d Cir. 1996) (following *Lujan*); *Association for Retarded Citizens of Dallas v. Dallas County Mental Health & Mental Retardation Ctr. Bd. of Trs.*, 19 F.3d 241, 244 (5th Cir. 1994) (same).

Or consider *Day v. Bond*, 500 F.3d 1127 (10th Cir. 2007), which addressed whether a Kansas law granting in-state tuition benefits to illegal aliens was preempted by a federal immigration statute. The Tenth Circuit held there was no standing because the immigration statute did not give rise to a private right of action: "The merits issue is whether [the Kansas statute] is preempted by 8 U.S.C. § 1623. The standing question is whether § 1623 creates a private cause of action. Each of these issues is separate and independent . . . ." *Id.* at 1136-39.

The same is true here. The merits question is whether Caraco's generic Lexapro would infringe Forest's '941 patent. The standing question is whether the civil action to obtain patent certainty ("CAPC") in 21 U.S.C. § 355(j)(5)(C) creates a private right of action apart from redressing disputes over infringement. The two questions are fully distinct, and the Federal Circuit was wrong to conclude that injury divorced from what is exclusively an infringement cause of action can support constitutional standing.[9]

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[9] *Day v. Bond*, which applies the analysis required by this Court's cases should be contrasted with outlier decisions, which reflect confusion about how to act on the principle that standing and merits analysis should be kept separate. *See, e.g., Club Italia Soccer & Sports Org., Inc. v. Charter Twp. of Shelby, Mich.*, 470 F.3d 286 (6th Cir. 2006). In that case, the Sixth Circuit assailed a district court decision that had held "because Plaintiff does not allege a legally protectable interest, Plaintiff does not have standing." *Id.* at 292. According to the Sixth Circuit, "[t]his conclusion improperly grafts the standing inquiry onto the merits of Plaintiff's due process claim." *Id.* Such an analysis harkens back to the outdated view that the existence of a legally protected right is irrelevant to

2. The Federal Circuit's principal error was to devise a cause of action of its own making, premised on a nonexistent right to seek review of any action by a pioneer drug company that contributed to preventing a generic company from marketing its drug as soon as possible. Relying on its earlier decision in *Novartis*, 482 F.3d at 1345, the Federal Circuit noted that "the Hatch-Waxman framework presents a different set of circumstances than those which underlie an ordinary infringement action." App. 24a. In most situations, the panel majority reasoned, the competitor of a patent holder can enter the market freely, but under Hatch-Waxman market entry must be authorized by the FDA. *See* 21 U.S.C. § 355(a). Thus, according to the panel, any action which contributes to "preventing the FDA from approving the ANDAs of generic drug manufacturers . . . . is a sufficient Article III injury-in-fact." App. 24a-25a.

This analysis effectively created a private right of action on the part of subsequent ANDA filers to sue for any action or inaction by a pioneering drug company that contributes to Hatch-Waxman's exclusion of generics from the marketplace while the 180-day exclusivity period for a first ANDA filer has not yet been triggered. But this newly minted, judicially created cause of action hardly resembles the civil action to obtain patent certainty created by Congress. Instead, CAPCs authorize only suits over

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demonstrating injury in fact. *Illinois. Citizens Comm. for Broad. v. FCC*, 515 F.2d 397, 413 (D.C. Cir. 1975) (separate statement by Bazelon, J., explaining why he voted in favor of en banc review). Movement in the lower courts in the direction of that discredited approach should be halted.

actual disputes concerning patent infringement or validity. 35 U.S.C. § 271(e)(5). Hence, once Forest gave Caraco a covenant not to sue, the CAPC right of action was terminated as a constitutionally cognizable controversy. *See infra* n.10. (Validity of the '941 patent was never in play because Caraco never even sought to challenge that patent on invalidity grounds.)

3. Recognizing that the covenant not to sue was problematic for its theory of standing, the Federal Circuit conceded that "[i]f a threat of suit was the *only action* allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case and divest the district court of Article III jurisdiction." App. 34a (emphasis added).[10] But, "in a manner that is unique to the Hatch-Waxman context," Forest injured Caraco because it listed the '941 patent with

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[10] This analytical move also allowed the panel majority to avoid running afoul of a long line of cases holding that the granting of a covenant not to sue for infringement moots a declaratory judgment action to resolve an infringement dispute. *See Apotex, Inc. v. Pfizer, Inc.*, 125 F. App'x 987, 987 (Fed. Cir. 2005) (per curiam); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1340-41 (Fed. Cir. 2001); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 1093 (1996). Indeed, just the year prior to handing down the decision in this case, the Federal Circuit had held that this line of cases did not depend on the "reasonable apprehension of suit" test disapproved in *MedImmune*. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007). Even applying *MedImmune*, *Benitec* reached the same essential conclusion. Yet the decision below did not distinguish, or even cite, *Benitec*.

the FDA and because it granted Caraco a covenant not to sue for infringement. App. 35a.

This ignores the critical fact that the only adverse action cognizable under the CAPC form of action in this case (where Caraco did not pursue a theory of patent invalidity) was a suit for infringement. Any other actions by Forest, no matter how injurious, cannot support standing because only a suit to declare rights in an infringement controversy can support constitutional standing. While Congress provided that the CAPC action should be interpreted as broadly as possible consistent with the bounds of Article III, *see* 35 U.S.C. § 271(e)(5), the Federal Circuit erred in converting that interpretive instruction into an authorization to create a freestanding cause of action for any injury experienced by ANDA filers traceable in any respect to the blocking patent holder.

4. The only way the panel's decision here could be correct is if injury "in the air" were sufficient to support Article III jurisdiction. It is not. *In re Asbestos Litig.*, 90 F.3d 963, 1020 & n. 70 (5th Cir. 1996) (Smith, J., dissenting) ("[S]tanding analysis does not operate in a vacuum: The allegation of a cause of action frames the inquiry . . . . we must examine the pleadings to determine what cause of action the plaintiff has alleged and whether his allegations of injury, in the context of that cause of action, satisfy Article III standards.").[11] *See also*

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[11] The petition for certiorari was granted in *In re Asbestos Litigation*, with the decision being vacated and remanded for reconsideration on statutory grounds in light of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). After remand, reversal by *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), of

International Primate Prot. League v. Administrators of Tulane Educ. Fund, 500 U.S. 72, 77 (1991) ("[S]tanding is gauged by the specific common-law, statutory or constitutional claims that a party presents."); *Catholic Social Serv. v. Shalala*, 12 F.3d 1123, 1125 (D.C. Cir. 1994) (similar); *Lujan*, 504 U.S. at 580 (Kennedy, J., concurring) ("In my view, Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before . . . .").

5. The decision below also is in conflict with the Federal Circuit's prior decisions. *See Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340-41 (Fed. Cir. 2007) (party that held insufficient rights in a patent lacked standing to sue because "[the plaintiff] is not the party to which the statutes grant judicial relief . . . . [the plaintiff] suffers no legal injury in fact to the patent's exclusionary rights.") (citing *Warth*); *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1308 (Fed. Cir. 2003) (plaintiff lacked Article III standing because it had insufficient legal interest in the patent to be considered "the patentee" under the Patent Act). Indeed, the author of this very opinion previously recognized that standing can only be founded upon the assertion of a viable cause of action. *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1346 (Fed. Cir. 2001) (Gajarsa, J.) (relying on *Lujan*, stating "TCI-California is correct in its assertion that Article III standing to sue in this case derives solely from

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the Fifth Circuit majority, fully vindicated the pre- and post-remand dissents of Judge Smith, albeit on grounds of a lack of "statutory standing." *Id.* at 831.

the Patent Act.").

In like manner, in a decision released just this September addressing a fact pattern very similar to this case, a *different* panel of the Federal Circuit appeared to recognize, in conflict with the holding here, the absence of a legally cognizable injury. In *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), the innovator pharmaceutical company (Janssen) listed three patents in the Orange Book and successfully defended against challenges brought by the first Paragraph IV ANDA filers to the earliest-expiring patent. *Id.* at 1357-58. In subsequent litigation between the innovator and another generic (Apotex), the generic stipulated that the earliest-expiring patent was valid and not infringed, and the innovator gave the generic a covenant not to sue on the other two patents. *Id.* at 1358-59. In that case, the Federal Circuit held that the generic's declaratory judgment claims with respect to the latter two patents were moot. *Id.* at 1360-61. The court stated that "Apotex's inability to launch its generic . . . because of Teva's 180-day exclusivity period *is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act.*" *Id.* (emphasis added).

The only significant difference between *Janssen* and this case—and the basis on which the *Janssen* panel purported to distinguish this case—is that Forest and Caraco are litigating Forest's earliest-expiring patent on Lexapro—the '712 patent—in a separate action. *Id.* at 1361. In petition-for-rehearing briefing, neither side in the *Janssen* litigation found this distinction entirely tenable. The losing generic company, of course, protested that

the instant case and *Janssen* were indistinguishable. But even prevailing party Janssen, the innovator drug company, argued in the alternative that the Federal Circuit decision here should be overruled in *Janssen* because both this suit and that suit are beyond the reach of Article III. Nevertheless, the Federal Circuit denied Apotex's petition for rehearing on October 29, 2008.

The ineluctable conclusion to be drawn from this cacophony of Federal Circuit precedent is that the court is deeply confused about the protectable-right requirement of *Lujan*, both generally and in the vitally important context of the Hatch-Waxman Act. Even when the Federal Circuit acknowledges the importance of legally protected rights to standing issues, it does not necessarily deploy the correct analysis. *See Willis v. GAO*, 448 F.3d 1341, 1349 (Fed. Cir. 2006) (only client had legally protected right to statutory attorney's fees and hence "the attorney [seeking to recover fees] fails to satisfy the requirements of *prudential standing*") (emphasis added). The emphasis in *McConnell*, *Lujan*, *International Primate*, and *Warth* on legally protected rights was *not* premised on prudential standing. To the contrary, it was premised upon the foundational requirements of Article III.

II. Contrary To Supreme Court And Circuit Law, The Federal Circuit's Decision Finds Standing Where Causation Is Fairly Traceable Only To Causes Beyond The Defendants' Control.

1. The Federal Circuit held that Caraco's injury is "fairly traceable" to Forest because "if Forest had not listed its '712 and '941 patents in the FDA's

Orange Book as valid patents covering the drug described in its NDA for Lexapro, then [the Hatch-Waxman Act] would not independently delay Caraco's ANDA from being approved by the FDA." App. 26a. "Such but-for causation," the court concluded, "is sufficient to satisfy the traceability requirement of Article III standing." *Id.* (citing *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26 (1978)).

In the full context of this case, however, the Federal Circuit's reliance on "but-for" causation is in tension with decisions of the Tenth Circuit and D.C. Circuit. *See Bronson v. Swensen*, 500 F.3d 1099 (10th Cir. 2007); *Fulani v. Brady*, 935 F.2d 1324 (D.C. Cir. 1991). Those courts have rejected but-for causation as sufficient to establish standing where, as here, the complained-of conduct leads to injury only by virtue of its combination with other, more dominant causes traceable to sovereign acts.

In *Bronson*, the plaintiffs filed a civil rights action against a county clerk for refusing to issue a marriage license that would have resulted in a polygamous union in violation of state criminal law. 500 F.3d at 1101. Although conceding that the clerk had no power to initiate criminal prosecutions, the plaintiffs argued that their injury was traceable to the county clerk because if the clerk issued a marriage license, then they arguably would be free from fear of criminal prosecution. *Id.* at 1110-11. The Tenth Circuit rejected plaintiffs' arguments because they were based on allegations that they would receive collateral benefits (freedom from criminal prosecution) if the clerk granted the license, not on any injury caused by the clerk. *Id.* at 1111.

Likewise, in *Fulani*, a minor-party presidential

candidate brought an action against the Internal Revenue Service challenging the tax-exempt status of the Commission for Presidential Debates, which had excluded her from the 1988 presidential debates. 935 F.2d at 1325. Under Federal Election Commission rules, the Commission could sponsor the debate only if it received tax-exempt status. *Id.* at 1325, 1330. The D.C. Circuit concluded that Fulani lacked standing to bring her challenge because the "IRS's actions caused her alleged injury only due to other intervening causal factors," including the FEC's regulations and Commission's actions. *Id.* at 1331. Even though Fulani's suit against the IRS, if successful, would have resulted in the Commission no longer being able to hold debates that excluded her as a participant, the D.C. Circuit rejected the argument that because Fulani's injury might be redressed by judgment against the IRS, the IRS must be deemed the cause of her injury.

In this case, by contrast, the Federal Circuit has taken the position that because Caraco's victory in a declaratory judgment suit against Forest could ameliorate Caraco's injury of delay in market entry, Forest's actions to grant a covenant not to sue and its compliance with the Hatch-Waxman Act listing mandate must be the causes of Caraco's injury. But the Federal Circuit's holding that a party's mandatory compliance with a statute can give rise to actionable injury by another party cannot be squared with the judgments of the Tenth and D.C. Circuits. Those courts properly recognize that Article III standing requires that the injury that is the subject of the suit be caused by the defendant that the plaintiff is suing. *Accord Lujan*, 504 U.S. at 560-61 ("[T]here must be a causal connection between the

injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action *of the defendant*, and not . . . th[e] result [of] the independent action of some third party not before the court.'") (emphasis added) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)).

In *Allen v. Wright*, 468 U.S. 737 (1984), *Simon*, and *Warth*, this Court held that the plaintiffs' injuries were not "fairly traceable" to the defendants where the chain of causation was broken by the actions of independent third parties. In *Allen* and *Simon*, the plaintiffs sued officers of the IRS, alleging that the Service's unlawful grants of tax exemptions to third parties led to the plaintiffs suffering injuries at the hands of the third parties. *See Allen*, 468 U.S. at 746 (explaining the chain of causation alleged in the complaint); *Simon*, 426 U.S. at 32-33 (same). In *Warth*, the plaintiffs alleged that a city's zoning ordinance led to their injury by making it more difficult for third parties to confer benefits on them. 422 U.S. at 495-97.

2. There is simply no basis for concluding that Forest's actions are the real cause of the injury the Federal Circuit posited Caraco suffers—exclusion from the market for generic Lexapro. This is true for several reasons.

First, the primary source of Caraco's inability to sell generic Lexapro is the Hatch-Waxman Act bar blocking the FDA from approving Caraco's ANDA until 180 days after (1) Ivax begins marketing its generic products; or (2) for each patent at issue, issuance of a decision of non-infringement or invalidity. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). That obstacle, however, is not of Forest's making. Rather,

it is the result of Congress's decision to encourage early challenges to patents listed in the Orange Book by rewarding the first generic to file a Paragraph IV certification, which inevitably comes at the expense of subsequent-filer generics. In this case, Ivax was the *first* filer on the '941 patent. Caraco was the *seventh*. Hence, by congressional decree, Caraco must wait until Ivax's exclusivity period has elapsed.

Second, Forest's challenged conduct—the listing of its patents in the Orange Book—is required by statute. 21 U.S.C. § 355(b)(1). Had Forest failed to list either of its patents, it would be subject to various penalties, including withdrawal of its own NDA approval and authorization to sell. *See* 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v) (1999); 21 C.F.R. § 314.53(b),(c) (2004). Indeed, the Hatch-Waxman listing obligation is backed forcefully by potential criminal sanctions. *See* 21 C.F.R. § 314.53(c)(2)(i)(Q) (2004) (failure to provide an accurate and complete submission of patent information in an NDA subjects the holder to criminal liability for perjury). Thus, to the extent that Forest's listing of its patents caused Caraco's injury, that is the consequence of yet another set of choices made by Congress, or by the FDA pursuant to delegated authority under Hatch-Waxman.

Third, as explained in Section I, *supra*, even if Forest's decision to avoid the expense and disruption of litigation concerning the '941 patent were a minor contributing cause of injury to Caraco, such a cause is not legally actionable. The reason is that Forest has no enforceable duty to refrain from granting irrevocable covenants not to sue and because, on the flip side of that point, Caraco has no valid cause of action to force Forest to retract its covenant.

3. The Federal Circuit majority accuses Forest of "gaming" the Hatch-Waxman Act system. App. 9a. Not so. It is wrong to presume that every decision by a pioneer drug holder to litigate regarding only one of its patents constitutes strategic behavior. Avoiding the costs, uncertainty, and disruption of litigation are legitimate ends in themselves.

Apparently, the court below thought that it was empowered to assume that any action by a pioneer drug company which might contribute to the delay of the introduction of generic competition violated Congress's purposes in enacting Hatch-Waxman and the Medicare Modernization Act amendments. App. 8a (discussing a pioneer drug company's "strong incentive to avoid litigation" so as to delay the onset of a first ANDA filer's exclusivity period).

But "no legislation pursues its purposes at all costs. . . . [I]t frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 525-526, (1987) (per curiam). The Federal Circuit majority itself recognized this when it pointed out that the purpose of Hatch-Waxman was to *balance* the interests of pioneer and generic drug companies. App. 3a. But by elevating a minor cause and ignoring the more dominant causes of the Hatch-Waxman restriction on market entry and the Act's requirement to list patents in the Orange Book, the majority below took it upon itself to rebalance Congress's policy choices as inherent in the limits on the cause of action for infringement as established in the CAPC form of suit. Or, as dissenting Judge Friedman recognized, "[t]o the extent that Congress may conclude that particular judicial interpretations

of the Act thwart the purposes of the legislation, it is for Congress, not this court, to make whatever changes in the Act it deems appropriate." App. 42a.

III. The Issues In This Case Are Exceptionally Important To Pharmaceutical Innovation And The Nation's Economy.

1. The Federal Circuit's decision threatens to disrupt the careful balance of incentives Congress created to ensure that the public will benefit from receiving the most pharmaceutical innovation at the lowest cost. The divided panel's decision creates a precedent of generalized significance concerning the effect of covenants not to sue on all future CAPC actions under the Hatch-Waxman Act, and thus will apply to all relevant patent disputes in this area. 28 U.S.C. § 1295(a)(1), (a)(4); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829 (2002).

The landmark Hatch-Waxman legislation amended both the food and drug and the patent laws to strike a careful balance between two competing policy objectives: (1) inducing innovators to make the investments necessary to develop new drugs, and (2) enabling generics to bring lower-cost versions of those drugs to market in a timely fashion. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

In furtherance of the latter objective, Congress encouraged generics to challenge innovators' patents as soon as possible by offering the incentive of 180 days of generic market exclusivity to the *first* ANDA

filer. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Importantly, Congress chose to protect the 180-day exclusivity period by forbidding the FDA from approving the applications of other generics. *Id.*

In the case at hand, the panel majority may have chosen to discount the value Congress placed upon incentives to first filers because it had the *ex post* knowledge that Ivax's patent litigation against Forest had failed. But that kind of *post hoc* analysis is improper because the incentives for first filers to bring patent challenges inevitably have to be set *ex ante* behind a veil of ignorance as to whether particular patent litigation will succeed or fail. From a "Monday-morning quarterback" perspective, it is easy to see why a court might want to give a chance to other generics to take their own separate shots at piercing a patent. But it frustrates the will of Congress to do anything other than faithfully and vigorously enforce the 180-day market exclusion the Article I branch established to incentivize first filers to mount patent challenges. *Cf. Hughes Aircraft Co. v. Jacobsen*, 525 U.S. 432, 447 (1999) ("[B]ecause ERISA is a comprehensive and reticulated statute, and is enormously complex and detailed, it should not be supplemented with extratextual remedies.") (citations and internal quotation marks omitted).

In this case, Ivax lunged at the incentive Congress established and assumed the substantial risk of bringing the *first* challenge to Forest's patents. Caraco, by contrast, choose to fall back deep into the queue. It waited a year to become the *seventh* ANDA filer to challenge Forest's '941 patent. Given Ivax's initiative and Caraco's opportunistic choice of waiting to see how infringement litigation between Forest and Ivax played out, Forest's

willingness to avoid further litigation by granting a covenant not to sue, together with the limited cause of action for infringement or invalidity created in the Medicare Modernization Act, add up to the nonexistence of an Article III controversy. In short, no tears should be shed for Caraco. Had it been the first ANDA filer, it would not be in a position where it lacks a viable cause of action and thus constitutional standing.

2. If the Federal Circuit's decision is allowed to stand, it will cause serious marketplace harm, diluting the incentives Congress created for both innovators and first-out-of-the-gate generics.

First, innovators like Forest will be forced to defend themselves in needless litigation against generics they have already promised not to sue. Indeed, the Federal Circuit never considered the practical implications of its holding. Can Forest be conscripted against its will to litigate against Caraco? Does interpreting the statute to have the effect of drafting Forest into an involuntary litigation role raise constitutional questions? Are there interpretations of Hatch Waxman that would avoid such an unprecedented interference in private litigation, in the fashion of *Ashwander v. TVA*, 297 U.S. 288, 348 (1936) (Brandeis, J.) ("[I]t is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the [constitutional] question may be avoided")? No satisfactory answers were provided (or even ventured) to these questions by the Federal Circuit.

Second, the boldest risk-taking generics most favored by Congress, such as Ivax, will witness a severe reduction of their incentives to engage in

costly patent challenges. As it explained in its *amicus* brief in support of rehearing below, "Ivax has a strong interest in protecting the exclusivity incentive against unproductive and self-serving challenges like Caraco's." Br. Amicus Curiae of Ivax Pharm., Inc. in Support of Rehearing at 3. "If generic companies can bring declaratory judgment actions directed to patents that they have no risk of infringing, and by so doing eliminate a competitor's marketing exclusivity, they will do so at every opportunity." *Id.* at 2-3. The serious practical problem, which Congress wisely calibrated the Hatch-Waxman regime to account for, is that a sidelines-sitting opportunist like Caraco has far less "skin in the game" than an incentivized challenger like Ivax.

Indeed, the balance of incentives Congress offered to innovators and generics is critically important to the public interest. In 2007, the American pharmaceutical industry spent an estimated $58.8 billion on research and development of new drugs. *See* Pharmaceutical Research & Manufacturers of America, PHARMACEUTICAL INDUSTRY PROFILE 2 (2008). On the other side of the scales, a 1998 study estimated that generic drugs save consumers between $8 and 10 billion per year. *See* Congressional Budget Office, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 31 (1998). In a poor exchange, the Federal Circuit's decision weakens the incentives in both sectors of the pharmaceutical industry so as to reward laggard generics. This is irrational and contrary to Congress's democratic choices (which are protected by the bulwark of Article III). Most

importantly, in undermining the incentives both to the development of new pioneering drugs and efforts by bold generics to weed out weak patents from the system, the divided panel decision below will inexorably inflict net harm on consumers and the public health.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted.

Respectfully submitted,

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November 6, 2008

APPENDIX

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CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff-Appellant,

v.

FOREST LABORATORIES, INC., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S, Defendants-Appellees.

No. 2007-1404.

United States Court of Appeals, Federal Circuit.

April 1, 2008.

Rehearing and Rehearing En Banc Denied June 24, 2008.

James F. Hurst, Winston & Strawn, LLP, of Chicago, IL, argued for plaintiff-appellant. With him on the brief were Derek J. Sarafa and Samuel S. Park. Of counsel on the brief were Steffen N. Johnson and Luke W. Goodrich, of Washington, DC.

Gerald J. Flattmann, Jr., Kirkland & Ellis LLP, of New York, NY, argued for defendants-appellees. With him on the brief were John M. Desmarais, Christine Willgoos, and Benjamin A. Lasky. Of counsel was Peter J. Armenio.

Before GAJARSA, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and PROST, Circuit Judge.

Opinion for the court filed by Circuit Judge GAJARSA. Dissenting opinion filed by Circuit Judge FRIEDMAN.

GAJARSA, Circuit Judge.

This is an action brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the provision of the Hatch-Waxman Act establishing civil actions for patent certainty, 21 U.S.C. § 355(j)(5)(C). Plaintiff-Appellant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") appeals a decision of the United States District Court for the Eastern District of Michigan dismissing its declaratory judgment action for noninfringement against Defendants-Appellees Forest Laboratories, Inc., et al., ("Forest"). Caraco's action was dismissed for lack of Article III jurisdiction on the grounds that it had been rendered moot when Forest unilaterally granted Caraco a covenant not to sue for infringement of the patent-in-suit, U.S. Patent No. 6,916,941. However, in the context of the Hatch-Waxman framework, Forest's covenant not to sue did not eliminate the controversy between the parties. Accordingly, we hold that Caraco's declaratory judgment action presents a continuing Article III controversy, and *reverse* and *remand* for further proceedings.

I. BACKGROUND

This case arises under the Hatch-Waxman Act,[1] which governs the Food and Drug Administration's ("FDA") approval of new and generic drugs. The goal of the Act is to "[strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). The following five aspects of the Hatch-Waxman framework are relevant to this case.

First, a pioneering drug company must obtain FDA approval for its drug by submitting a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a), (b). As part of the NDA process, the drug company must inform the FDA of all patents covering its drug or the methods of using the drug, "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists all such patents in a publication titled the "Approved Drug Products With Therapeutic Equivalence Evaluations." This publication is commonly known as the "Orange Book." Drugs

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[1] The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

approved by the FDA are known as "listed drugs." *See* 21 U.S.C. § 355(j)(2)(A)(i).

Second, to facilitate the development of generic versions of listed drugs, the Hatch-Waxman Act provides an Abbreviated New Drug Application ("ANDA") process for generic drug manufacturers. *See* 21 U.S.C. § 355(j). The ANDA process streamlines FDA approval of generic drugs by allowing applicants to rely on the results of the safety and efficacy studies that supported the FDA's approval of a listed drug. *See id.; Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S. Ct. 2683, 110 L. Ed.2d 605 (1990). Under the ANDA process, a generic drug company must submit information to show, inter alia, that its generic drug and the relevant listed drug share the same active ingredients and are bioequivalent. 21 U.S.C. § 355(j)(2)(A)(ii), (iv). In addition, generic drug companies must submit one of four certifications addressing each Orange-Book-listed patent covering the listed drug. Specifically, the ANDA filer must certify –

> (I) that [the required] patent information has not been filed [with the FDA],
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). If a generic drug company seeks to market a generic version of a listed drug before the expiration of Orange-Book-listed patents covering that drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e. a "Paragraph IV certification." *See Eli Lilly*, 496 U.S. at 677, 110 S. Ct. 2683. All Paragraph IV ANDA filers must provide notice of their Paragraph IV certification to both the patent owner and the NDA holder. 21 U.S.C. § 355(j)(2)(B). This notice must set forth a "detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

Third, the Hatch-Waxman Act facilitates the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2); *Eli Lilly*, 496 U.S. at 678, 110 S. Ct. 2683. The Act states that "it shall be an act of infringement" to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2). As this court has explained, "§ 271(e)(2) is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004) (emphasis in original); *see also Eli Lilly*, 496 U.S. at 678, 110 S. Ct. 2683 ("Quite obviously, the purpose of subsection[ ] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme[ ] depend[s].")

Fourth, to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification ("first Paragraph IV ANDA filer") shall enjoy a 180-day period of generic marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Until the first Paragraph IV ANDA filer's exclusivity period expires, the FDA may not approve a later-filed Paragraph IV ANDA based on the same NDA (hereinafter a "subsequent Paragraph IV ANDA"). *Id.* Importantly, the first Paragraph IV ANDA filer is entitled to the 180-day exclusivity period whether or not it establishes that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its ANDA; all that is required is that the first Paragraph IV ANDA filer submit a substantially complete ANDA that contains a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

The Hatch-Waxman Act provides that the 180-day period of exclusivity begins either on the date that the first Paragraph IV ANDA filer begins marketing its generic drug, or on the date of a final court decision finding the relevant Orange-Book-listed patents invalid or not infringed, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000)[2];

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[2] In 2003, Congress replaced the provisions governing the commencement of the 180-day exclusivity period with a new regime under which the first Paragraph IV ANDA filer can forfeit its exclusivity period if it fails to market its drug within a certain time. *See* 21 U.S.C. § 355(j)(5)(D); *see also Pfizer*, 395 F.3d at 1329. The amendment was part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("Medicare

see also Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1328 (Fed. Cir. 2005) ("*Pfizer*"). In other words, the applicable statutory provisions provide for two methods of triggering the first Paragraph IV ANDA filer's 180-day exclusivity period: (1) a commercial-marketing trigger pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000) and (2) a court-judgment trigger pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Only the first Paragraph IV ANDA filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I). However, subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002) ("*3M*") (holding that the first Paragraph IV ANDA filer's 180-day exclusivity period can be triggered by a court judgment obtained by a subsequent Paragraph IV ANDA filer).

Modernization Act" or "MMA"), which was enacted on December 8, 2003. *Pfizer*, 395 F.3d at 1328-29. Despite these changes, the MMA contained a grandfather provision specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of enactment of the MMA. *See* MMA § 1102(b). The amendments also do not apply if another generic drug company had filed a Paragraph IV ANDA for the same listed drug before the date of enactment of the MMA. *Id.* In this case, a generic drug company, namely Ivax Pharmaceuticals, Inc., filed a Paragraph IV ANDA in August 2003, before the December 2003 enactment of the MMA. Thus, the MMA amendments to the provisions governing the commencement of 180-day exclusivity period are inapplicable to this case.

Since the FDA cannot approve subsequent Paragraph IV ANDAs until the first Paragraph IV ANDA filer's 180-day exclusivity period expires, the date on which the exclusivity period is triggered is critical to NDA holders and subsequent Paragraph IV ANDA filers. On the one hand, subsequent Paragraph IV ANDA filers have a strong incentive to generate a triggering event allowing the FDA to approve their subsequent Paragraph IV ANDAs 181 days after the triggering event. On the other hand, NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity period expires. Moreover, because subsequent Paragraph IV ANDA filers can only activate the first Paragraph IV ANDA filer's 180-day exclusivity period through the court-judgment trigger, subsequent Paragraph IV ANDA filers have a strong incentive to challenge the NDA holder's Orange-Book-listed patents in court. Conversely, NDA holders have a strong incentive to avoid litigation that would trigger the first Paragraph IV ANDA filer's exclusivity period and allow the FDA to approve subsequent Paragraph IV ANDAs 181 days after the triggering event.

For example, if a first Paragraph IV ANDA filer is found liable in a § 271(e)(2) infringement action or simply fails to market its generic drug, then it has not triggered its own exclusivity period through the court-judgment trigger or the commercial-marketing trigger. In that case, a subsequent Paragraph IV ANDA filer must generate a court-judgment triggering event in order to activate the first Paragraph IV ANDA filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); *3M*, 289 F.3d at 780. More precisely, the subsequent

Paragraph IV ANDA filer must obtain a judgment that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its subsequent Paragraph IV ANDA. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). However, if the NDA holder can prevent the subsequent Paragraph IV ANDA filer's court challenge, it can delay FDA approval of the subsequent Paragraph IV ANDA and thus delay the subsequent Paragraph IV ANDA filer's entry into the market. *See* 21 U.S.C. § 355(a) (providing that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an [NDA or ANDA] is effective with respect to such a drug") Indeed, an NDA holder could thus delay any subsequent Paragraph IV ANDA filer from entering the market until the NDA holder's Orange-Book-listed patents expire.[3]

The fifth and final aspect of the Hatch-Waxman Act relevant to this case is the "civil action to obtain patent certainty" ("CAPC"). *See* 21 U.S.C. § 355(j)(5)(C). The CAPC is designed to prevent NDA holders from "gaming" the Hatch-Waxman Act by forestalling the resolution of patent disputes with ANDA filers. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) ("*Novartis*"). Under the CAPC provisions, if the NDA holder fails to sue a Paragraph IV ANDA filer within 45 days, the ANDA filer can sue the NDA

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[3] Generic drug companies can obtain immediate FDA approval of their drugs when the relevant Orange-Book-listed patents expire by submitting a Paragraph III ANDA certifying that the patents will expire on that date. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

holder to obtain a declaratory judgment that the relevant Orange-Book-listed patents are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C).

In addition, Congress extended federal jurisdiction over CAPCs "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Accordingly, federal courts have jurisdiction over CAPCs to the extent that they present an Article III case or controversy. *Novartis*, 482 F.2d at 1342. Congress explained the need for broad federal jurisdiction over CAPCs as follows:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.[4]

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[4] The discussion here refers to the "failure to market" provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(D), under which the first Paragraph IV ANDA filer can forfeit its 180-day exclusivity period by failing to market its generic drug. Section 355(j)(5)(D) replaced the 180-day exclusivity period triggering provisions that are applicable to this case, i.e. 21 U.S.C. § 355(j)(5)(B)(iv) (2000), including the court-judgment trigger. *See supra* note 2 (discussing MMA § 1102(b), 117 Stat. at 2460). Although the legislative discussion here refers to the amended 180-day provisions, this distinction is inconsequential because under both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed. Thus, Senator Kennedy's remarks

> In . . . these . . . circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. *We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.* The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions) (emphasis added).

II. FACTS

A. Forest's NDA for Lexapro®

Forest holds an approved NDA for its drug Lexapro®, which is used to treat depression and generalized anxiety disorder. Forest currently faces no generic competition for Lexapro®. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 438 F. Supp. 2d 479, 494 (D. Del. 2006).

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concerning the brand name drug company's incentive to delay such court decisions are equally applicable to this case.

As part of the process for filing its Lexapro® NDA, Forest listed two patents in the FDA's Orange Book, namely: U.S. Patent Nos. Re. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). The '712 patent includes claims covering substantially pure forms of escitalopram, the active ingredient of Lexapro®. The '941 patent generally covers crystalline particles of escitalopram oxate of a particular size range, as well as dosage forms containing particles of this size range, and methods of manufacturing particles in this size range. The '712 patent expires in 2012; the '941 patent expires in 2023.

B. The First Paragraph IV Challenge to Forest's Orange-Book-Listed Patents for Lexapro® and the Consequences for Subsequent Paragraph IV ANDA Filers

The first ANDA applicant to file a Paragraph IV certification for Forest's '712 and '941 patents was Ivax Pharmaceuticals, Inc. ("Ivax"). Accordingly, Ivax is entitled to 180 days of generic market exclusivity, which will begin either on the day it begins marketing its generic drug, or on the date a court determines that the '712 and '941 patents are invalid or not infringed – whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

Forest responded to Ivax's Paragraph IV ANDA by suing Ivax for infringement of the '712 patent, the earlier of the two patents to expire. Ivax counterclaimed that the '712 patent was invalid. Despite suing Ivax on the '712 patent, Forest did not sue Ivax for infringement of the '941 patent. By holding the '941 patent in reserve, Forest insulated

itself from an invalidity or noninfringement challenge by Ivax.[5] Ultimately, Forest defeated Ivax's counterclaim of invalidity on the '712 patent and obtained a judgment that the drug described in Ivax's ANDA infringed the '712 patent, which was affirmed by this court in *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

In sum, after filing a Paragraph IV certification for both the '712 and '941 patents in its ANDA, Ivax failed to obtain a court judgment that either the '712 or the '941 patent is invalid or not infringed by the drug described in its ANDA. Because Ivax has not obtained a judgment that both of Forest's Orange-Book-listed patents are invalid or not infringed by the generic drug described in its ANDA, Ivax failed to trigger its 180-day exclusivity period via the court-judgment trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000).

In addition, because the generic drug described in Ivax's ANDA was found to infringe the '712 patent, Ivax cannot trigger its 180-day exclusivity period via the commercial-marketing trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000), until the '712 patent

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[5] As will be discussed in more detail later, in *Novartis* this court held that where an NDA holder brings an infringement suit against a Paragraph IV ANDA filer on only one of several Orange-Book-listed patents covering its NDA, the ANDA filer has standing to seek a declaratory judgment on any of the NDA holder's remaining Orange-Book-listed patents for that NDA. 482 F.2d at 1346. However, *Novartis* had not been decided at the time of Forest and Ivax's dispute, and in any case, Ivax never sought a declaratory judgment that Forest's '941 patent was invalid or not infringed by its generic drug, *see Ivax Pharms., Inc.*, 501 F.3d at 1265.

expires in 2012. Indeed, the district court specifically enjoined Ivax from "making, using, offering to sell or selling within the United States, or importing into the United States any products that infringe the '712 patent, including the [drug] products referred to in [Ivax's ANDA] until such time as the '712 patent expires . . . ." *Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF (D. Del. Nov. 3, 2006) (Judgment Order). As a result, Ivax cannot activate its exclusivity period via the commercial-marketing trigger until the '712 patent expires.

With Ivax no longer able to trigger its exclusivity period, only two pathways remain open to subsequent Paragraph IV ANDA filers who seek to trigger Ivax's exclusivity period before the '712 patent expires in 2012. First, a subsequent Paragraph IV ANDA filer could obtain a court judgment invalidating the '712 patent, which would allow the FDA to approve Ivax's drug. With FDA approval, Ivax would be legally free to sell its generic drug, and its exclusivity period would be triggered on the day of its first commercial marketing. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000) (the "commercial-marketing trigger"). Second, a subsequent Paragraph IV ANDA filer could trigger Ivax's exclusivity period immediately—regardless of when Ivax begins marketing its drug—via the court-judgment trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). However, because Ivax was the first Paragraph IV ANDA filer with respect to both the '712 and '941 patents, a subsequent Paragraph IV ANDA filer can only activate Ivax's exclusivity period via the court-judgment trigger by obtaining a judgment that both the '712 and '941 patents are invalid or not infringed.

If a subsequent Paragraph IV ANDA filer is not able to pursue either of these two pathways to triggering Ivax's exclusivity period, then Ivax's exclusivity period cannot begin until the '712 patent expires in 2012. Moreover, assuming there has been no other triggering event by that time, Ivax's exclusivity period will not be triggered on the date the '712 patent expires unless Ivax actually begins marketing its generic drug on that date. Even if Ivax does so, the FDA will still be restricted from approving any subsequent Paragraph IV ANDA until 181 days after the date the '712 patent expires.[6] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

In short, absent an event triggering Ivax's exclusivity, all subsequent Paragraph IV ANDA filers, including Caraco, will be denied entry to the drug market for a significant time. These subsequent Paragraph IV ANDA filers will be precluded from the market regardless of whether the generic drugs described in their ANDAs infringe Forest's Orange-Book-listed patents and regardless of whether Forest's patents are valid.

C. Caraco's Subsequent Challenge to Forest's Orange-Book-Listed Patents for Lexapro®

In May 2006, Plaintiff-Appellant Caraco filed an ANDA for generic escitalopram that included a

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[6] When the '712 patent expires, subsequent Paragraph IV ANDA filers will not be able to obtain immediate FDA approval by filing a Paragraph III certification; obtaining FDA approval by filing a Paragraph III certification will not be an option until Forest's other Orange-Book-listed patent covering Lexapro®, the '941 patent, expires in 2023. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

Paragraph IV certification for Forest's '712 and '941 patents for Lexapro®. Under 35 U.S.C. § 271(e)(2), this constituted a technical act of infringement of both patents. Forest sued Caraco for infringement of the '712 patent in a lawsuit filed in the Eastern District of Michigan, *Forest Labs., Inc., v. Caraco Pharm. Labs., Ltd.*, Case No. 2:06-EV-13143-BAF-MKM.[7] As of the time of this writing, the parties' litigation with respect to the '712 patent is ongoing.

Despite suing Caraco for infringement of the '712 patent, Forest did not sue Caraco on the '941 patent. However as discussed above, under the Hatch-Waxman framework Caraco has an economic interest in determining whether the '941 patent is invalid or not infringed by the drug described in its ANDA, because only a judgment of invalidity or noninfringement with respect to both the '712 and '941 patents can trigger Ivax's exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Accordingly, Caraco filed a separate action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the Hatch-Waxman provision establishing the CAPC, 21 U.S.C. § 355(j)(5)(C), seeking a declaratory judgment that the drug described in its ANDA does not infringe Forest's '941 patent. Caraco's

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[7] It should be noted that by suing Caraco for infringement of the '712 patent, Forest triggered the automatic 30-month stay of FDA approval provided in 21 U.S.C. § 355(j)(5)(B)(iii). Under § 355(j)(5)(B)(iii), "[i]f the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires." *Pfizer*, 395 F.3d at 1328.

declaratory judgment action with respect to the '941 patent is the case presently on appeal.

Shortly after Caraco sued Forest for a declaratory judgment on the '941 patent, Forest filed a motion to dismiss Caraco's action pursuant to Fed. R. Civ. P. 12(b)(1) on the grounds that the action did not present a "case" or "controversy" as required by Article III of the Constitution. In its motion, Forest argued that there was no controversy because Caraco did not have a reasonable apprehension of suit on the '941 patent. At the time Forest filed its motion, this court's most recent precedent governing the justiciability of declaratory judgment suits applied the reasonable-apprehension-of-suit test to determine whether a justiciable controversy existed. *See, e.g.*, *Pfizer*, 395 F.3d at 1332. However, as is discussed in more detail below, even before Forest filed its motion, the Supreme Court found the reasonable-apprehension-of-suit test inconsistent with its precedent. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, n.11, 127 S. Ct. 764, 774 n.11, 166 L. Ed. 2d 604 (2007). The Court explained in *MedImmune* that whether a declaratory judgment action presents an Article III controversy must be determined based on "all the circumstances," not merely on whether the declaratory judgment plaintiff is under a reasonable apprehension of suit. *Id.* at 771.

In addition, after Forest filed its motion to dismiss but before the district court made its ruling, this court issued its decision in *Novartis*, 482 F.3d 1330. As in the present case, the issue in *Novartis* was whether a Paragraph IV ANDA filer's declaratory judgment action against an NDA holder presented a justiciable Article III case or

controversy. *Id.* at 1335. In *Novartis*, Teva Pharmaceuticals USA, Inc. ("Teva") was the first ANDA applicant to file a Paragraph IV certification on all five Orange-Book-listed patents covering an FDA approved drug owned by Novartis Pharmaceuticals Corp. ("Novartis"). *Id.* at 1334. Although Teva had filed a Paragraph IV certification for all five of Novartis' Orange-Book-listed patents, Novartis only brought suit under 25 U.S.C. § 271(e)(2)(A) for infringement of one of those patents.[8] *Id.*

After Novartis filed suit, Teva brought a separate action against Novartis on the four remaining Orange-Book-listed patents. *Id.* at 1335. However, the district court dismissed Teva's declaratory judgment action for lack of a justiciable controversy on the grounds that Teva had no reasonable apprehension of suit on the four remaining Orange-Book-listed patents. *Id.* This dismissal was the subject of the appeal in *Novartis*. *Id.* On appeal, the court observed that the Supreme Court's *MedImmune* decision had abrogated the reasonable-apprehension-of-suit test, *Novartis*, 482 F.3d at 1339, and applying the Supreme Court's all-the-circumstances test, the court found that there was a justiciable controversy between the parties, *Id.* at 1346. In reaching this decision, the court held that—

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[8] Even though Novartis only sued Teva on one of its Orange-Book-listed patents, this was sufficient to trigger a 30-month stay barring Teva's ANDA from approval under 21 U.S.C. § 355(j)(5)(B)(iii). *Novartis*, 482 F.3d at 1340 n.5.

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

Id. at 1344.

In thus applying the all-the-circumstances test to a declaratory judgment action between an ANDA filer and a pharmaceutical patentee, the *Novartis* decision eliminates Forest's argument that Caraco's declaratory judgment action should be dismissed because Caraco had no reasonable apprehension of suit on the '941 patent. After the *Novartis* decision issued, Forest unilaterally granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent. Forest's stated goal in granting the covenant to Caraco was "to confirm" that there was no case or controversy between the parties regarding the '941 patent. Forest's covenant provides, in relevant part:

> [Forest] hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged

> infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use, sale, offer for sale or importation of the generic products described by ANDA 78-219.

Notably, despite giving Caraco this covenant not to sue, Forest refused to concede that the '941 patent was invalid or not infringed by the drug described in Caraco's ANDA. In fact, Forest hinged its entire argument for dismissal on the covenant not to sue, stating: "There is no controversy because we gave a covenant not to sue." The district court agreed, stating from the bench that "[t]here's a covenant not to sue on the '941 so there's not going to be any loss, *there's no threat of lawsuit*." Transcript of Hearing on Motion to Dismiss at 31 (May 30, 2007) (emphasis added). On this basis, the district court ruled that there was no Article III controversy and granted Forest's motion to dismiss. Notably, there is no indication in the record that the district court considered either the Supreme Court's *MedImmune* decision or this court's *Novartis* decision when making this ruling.

III. ANALYSIS

A district court's dismissal of a declaratory judgment action for lack of jurisdiction presents a question of law that this court reviews de novo. *Novartis*, 482 F.3d at 1335.

Our starting point in analyzing Caraco's appeal is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), under which Caraco filed this suit. The relevant text of the Act provides:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). It is well established that the phrase "actual controversy" in § 2201(a) includes any controversy over which there is Article III jurisdiction. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40, 57 S. Ct. 461, 81 L. Ed. 617 (1937) (noting that "the word 'actual' is one of emphasis rather than of definition"). In addition, with respect to declaratory judgment actions brought by Paragraph IV ANDA filers against NDA holders to establish noninfringement or invalidity of Orange-Book-listed patents, Congress has specifically granted federal courts subject matter jurisdiction "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Thus, federal courts have subject matter jurisdiction over such actions to the extent that they present an Article III case or controversy. *See Novartis*, 482 F.3d at 1337.

In *MedImmune*, the Supreme Court reaffirmed the proper standard for determining whether a declaratory judgment action satisfies the Article III case or controversy requirement. 127 S. Ct. at 771. Specifically, the Court framed the justiciability inquiry as "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.*

(quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941)). In addition, the Supreme Court emphasized that Article III requires that the dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Id.* (quoting *Aetna Life Ins.*, 300 U.S. at 240-41).

In *Novartis* this court held that we must "follow *MedImmune's* teaching to look at 'all the circumstances' to determine whether [an action for a declaratory judgment of noninfringement or patent invalidity presents] a justiciable Article III controversy." 482 F.3d at 1339. Accordingly, *Novartis* acknowledged that this court's reasonable-apprehension-of-suit test was overruled by *MedImmune*. *Id.*; *see also SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380 (Fed. Cir. 2007). The reasonable-apprehension-of-suit test required "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity." *Novartis*, 482 F.3d at 1339. Following *MedImmune*, proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy.

In applying the all-the-circumstances test to Caraco's declaratory judgment action, we are guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy. In particular, an action is justiciable under Article III only where (1) the plaintiff has standing, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992), (2) the issues presented are ripe for judicial review, *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967), and (3) the case is not rendered moot at any stage of the litigation, *United States Parole Comm'n. v. Geraghty*, 445 U.S. 388, 397, 100 S. Ct. 1202, 63 L. Ed. 2d 479 (1980). For the following reasons, we hold that Caraco's declaratory judgment action satisfies these requirements and presents a justiciable Article III controversy.

A. Standing

The Supreme Court has explained that the "irreducible constitutional minimum of standing" contains the following three requirements:

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact"—a harm suffered by the plaintiff that is "concrete" and actual or imminent, not "conjectural" or "hypothetical." Second, there must be causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability—a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102-03, 118 S. Ct. 1003, 140 L. Ed. 2d 210 (1998) (internal citations omitted).

1. Caraco Alleges a Judicially Cognizable Injury-in-Fact

In this case, as in most declaratory judgment actions in the patent context, Caraco's alleged injury-in-fact is a "restraint on the free exploitation of non-infringing goods," *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998). Here, Caraco alleges it is being excluded from selling a non-infringing product because Forest has taken actions that delay the FDA from approving Caraco's ANDA. *See Novartis*, 482 F.3d at 1340 (observing that an ANDA filer suffers the requisite injury-in-fact where its ability to secure approval of its ANDA has been prevented by an NDA holder).

As this court explained in *Novartis*, the Hatch-Waxman framework presents a different set of circumstances than those which underlie an ordinary infringement action: "Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer . . . is not legally free to enter the market [without FDA approval]." 482 F.3d at 1345. Indeed, 21 U.S.C. § 355(a) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an [NDA or ANDA] is effective with respect to such a drug." Thus, by preventing the FDA from approving the ANDAs of generic drug manufacturers, pharmaceutical patentees like Forest can potentially exclude non-infringing generic

drugs from the market. If Caraco is correct that its generic drug does not infringe Forest's '941 patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact. Moreover, the fact that Forest's actions can only exclude Caraco from the drug market in the context of the Hatch-Waxman framework does not render Caraco's injury any less "concrete, actual or imminent." *Steel Co.*, 523 U.S. at 102-03.

In sum, Caraco alleges that it has been "restrain[ed from] the free exploitation of non-infringing goods," *Red Wing Shoe*, 148 F.3d at 1360. This is exactly the type of injury-in-fact that is sufficient to establish Article III standing under our caselaw. *See id.*; *see also Novartis*, 482 F.3d at 1345 (explaining that an NDA holder's use of an Orange-Book-listed patent to exclude a generic drug maker from the market creates "the exact type of uncertainty of legal rights that the ANDA declaratory judgment action [i.e. the CAPC, 21 U.S.C. § 355(j)(5)(C)] was enacted to prevent").[9]

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[9] Even before the *MedImmune* and *Novartis* decisions, the District of Columbia Circuit came to a similar conclusion. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998). In *Mova*, the court made the following observation:

> [T]he Federal Circuit has had no occasion to decide whether there is "a controversy of sufficient immediacy and reality" to support a declaratory judgment action, when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's

2. Caraco's Injury Is Traceable to Forest

Caraco's injury is also "fairly traceable [to] the complained-of conduct of the defendant," *Steel Co.*, 523 U.S. at 102-03. It is not the Hatch-Waxman Act or the FDA framework that prevents Caraco's ANDA from being approved by the FDA, but rather Forest's actions in the context—i.e. "under all the circumstances," *MedImmune*, 127 S. Ct. at 771—of the Hatch-Waxman framework. Simply put, if Forest had not listed its '712 and '941 patents in the FDA's Orange Book as valid patents covering the drug described in its NDA for Lexapro®, then 21 U.S.C. § 355(j)(5)(B)(iv) (2000) would not independently delay Caraco's ANDA from being approved by the FDA. Such but-for causation is sufficient to satisfy the traceability requirement of Article III standing. *See Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26, 98 S. Ct. 2620, 57 L. Ed. 2d 595 (1978).

As discussed above, where the first Paragraph IV ANDA filer has failed to trigger its own 180-day exclusivity period, the NDA holder's listing of Orange-Book patents delays a subsequent Paragraph IV ANDA filer from entering the marketplace indefinitely. Moreover, this delay occurs even if the drug described in the subsequent

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> express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

Id. (internal citation omitted).

Paragraph IV ANDA does not infringe the Orange-Book-listed patents. Here, Forest's listing of the '712 and '941 patents in the Orange-Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed by its generic drug. Under these circumstances, Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete. It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing. *See, e.g., Ne. Fla. Chapter, Associated Gen. Contractors of Am. v. Jacksonville*, 508 U.S. 656, 666, 113 S. Ct. 2297, 124 L. Ed. 2d 586 (1993) (holding that the "imposition of [a] barrier" to bid for certain government contracts satisfied the injury-in-fact and causation requirements of Article III standing); *Clements v. Flashing,* 457 U.S. 957, 962, 102 S. Ct. 2836, 73 L. Ed. 2d 508 (1982) (holding that the imposition of an "obstacle to [plaintiff's] candidacy for higher judicial office" satisfied the injury-in-fact and causation requirements of Article III standing); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 124-25, 89 S. Ct. 1562, 23 L. Ed. 2d 129 (1969) (holding that the plaintiff had standing to sue where it alleged that it had been denied a share of the market).

3. Caraco's Injury Is Redressible by a Favorable Judgment

Finally, Caraco's injury-in-fact is redressible by a declaratory judgment that the '941 patent is not

infringed.[10] A favorable judgment in this case would clear the path to FDA approval that Forest's actions would otherwise deny Caraco—namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) to activate Ivax's exclusivity period. If Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible. Thus, a favorable judgment in this action would eliminate the potential for the '941 patent to exclude Caraco from the drug market.[11]

* * *

In sum, Caraco's declaratory judgment action satisfies the injury-in-fact, causation, and redressibility requirements of standing. Moreover, even beyond satisfying the requirements of Article III standing, Caraco's action is consistent with the basic purpose of the Declaratory Judgment Act. As this court has previously explained, "the purpose of

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[10] Caraco's injury-in-fact would also be redressed by a judgment that the '941 patent is invalid, but Caraco has not sought a judgment of invalidity in this case.

[11] Although we do not so decide, it appears that if Forest would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent, such a decree would redress Caraco's alleged injury-in-fact just as well as any other court judgment. Thus, if Forest's objective in granting the covenant not to sue on the '941 patent was to avoid costly litigation with Caraco, this might be the best approach to resolve the controversy between the parties.

the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987); *see also Novartis*, 482 F.3d at 1336 n.2 ("The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) 'serve[] the policies underlying the patent laws by enabling a test of the validity and infringement of patents that are . . . being used only as . . . scarecrows.'" (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem*, 846 F.2d 731, 735 (Fed. Cir. 1988))).

In claiming that it has been denied the right to sell non-infringing generic drugs, Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy. *See Goodyear Tire & Rubber Co.*, 824 F.2d at 956; *Red Wing Shoe*, 148 F.3d at 1360; *see generally* E. Borchard, *Declaratory Judgments* 803-04 (2d ed. 1941) (discussing the history of the Declaratory Judgment Act). In particular, Caraco alleges that Forest's actions exclude it from the market without ever subjecting Forest's '941 patent to a court determination of its scope.[12] Caraco essentially argues that Forest's actions may allow it to "use a restricted [i.e. narrowly drafted] patent to justify much wider claims of infringement," E. Borchard, *supra*, at 803-04. Indeed, Caraco claims that it is being excluded from the drug market by Forest's '941 patent even though the generic drug described in its ANDA may not infringe the '941 patent.

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[12] As noted earlier, in the present action Caraco does not seek a judgment that the '941 patent is invalid.

Finally, Caraco's declaratory judgment action is also consistent with the basic goal of the Hatch-Waxman Act, which is to balance the need for pharmaceutical innovation with the need for generic drug competition. *Andrx Pharms., Inc.*, 276 F.3d at 1371. As previously noted, a significant part of this carefully crafted dialectic balance is encouraging the early resolution of patent disputes when subsequent Paragraph IV ANDA filers are "blocked by a first generic applicant's 180-day exclusivity." *See* 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).[13]

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[13] Both the dissent and Forest contend that the legislative history of the Hatch-Waxman Act supports the argument that the covenant not to sue moots any and all controversy with Caraco. The legislative history to which the dissent and Forest cite are the following remarks by Senator Edward Kennedy:

> We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a Paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. *We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.*

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions) (emphasis added).

B. Ripeness

Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.*, 387 U.S. at 149, 87 S. Ct. 1507. As to the first prong, an action is fit for judicial review where further factual development would not "significantly advance [a court's] ability to deal with the legal issues presented." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 812, 123 S. Ct. 2026, 155 L. Ed. 2d 1017 (2003). As to the second prong, withholding court consideration of an action causes hardship to the plaintiff where the complained-of conduct has an "immediate and substantial impact" on the plaintiff. *Gardner v. Toilet Goods Ass'n*, 387

Despite the arguments of the dissent and Forest, Senator Kennedy's remarks regarding the effect of a covenant not to sue were made when this court applied a "reasonable-apprehension-of-suit" test as the sole test for whether an action seeking a declaratory judgment of invalidity or noninfringement presented a justiciable Article III controversy. *See, e.g., Pfizer*, 395 F.3d at 1332. Under the reasonable-apprehension-of-suit test, a covenant not to sue would eliminate the controversy between the parties because the generic drug applicant would no longer have a reasonable apprehension of suit by the patentee. However, as discussed earlier, this singular approach to the justiciability of declaratory judgment actions was struck down by the Supreme Court in *MedImmune*, 127 S. Ct. at 774 n.11. Given this background, Senator Kennedy's comments only emphasize Congress's intent that the jurisdiction of federal courts to resolve CAPCs would extend to the limits of the Constitution. 35 U.S.C. § 271(e)(5). Moreover, it is ultimately the province and duty of the judicial department, not Congress, to discern the limits of Article III jurisdiction. *See Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177, 2 L. Ed. 60 (1803).

U.S. 167, 171, 87 S. Ct. 1526, 18 L. Ed. 2d 704 (1967).

In this case, both prongs of the ripeness inquiry are satisfied. First, additional factual development would not advance the district court's ability to decide Caraco's action for a declaratory judgment of noninfringement. Caraco has a complete generic drug product that has been submitted to the FDA for approval, and no additional facts are required to determine whether this drug product infringes the claims of Forest's '941 patent. Second, if Caraco's drug does not infringe Forest's '941 patent, then withholding court consideration of Caraco's declaratory judgment action has the "immediate and substantial impact" of forestalling Caraco's ability to activate Ivax's exclusivity period through the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000).[14] As noted earlier, only a judgment of

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[14] The dissent concludes that delaying resolution of this suit will have no immediate and substantial impact on Caraco. Indeed, the dissent states that the majority opinion "is highly speculative and conjectural, and involves uncertain legal issues that have not yet been resolved." With all due respect, we disagree. The dissent offers three main reasons to support its conclusion, and we will address each in turn.

First, the dissent states that there is "no basis to conclude that the first-filing generic manufacturer will, or is likely to, delay bringing its product to market after the '712 patent expires." We agree. What the dissent fails to recognize, however, is that the injury upon which Caraco's suit is premised is the delay (in triggering Ivax's exclusivity period) between now and when the '712 patent expires in 2012, not any delay (in triggering Ivax's exclusivity period) after the '712 patent expires. Thus, the dissent is in error when it notes that our analysis requires speculating as to when Ivax decides to market its drug after the '712 patent expires.

invalidity or noninfringement with respect to both the '712 and '941 patents can trigger Ivax's exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Thus, if Caraco's drug does not infringe Forest's '941 patent, then delaying court consideration of Caraco's declaratory judgment action on the '941 patent delays the date on which the FDA is authorized to approve Caraco's ANDA. Specifically, Caraco would be delayed until at least 181 days after the '712 patent expires in 2012. Because Caraco cannot market its generic drug without FDA approval, being delayed from resolving its claim to noninfringement of the '941 patent

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Second, the dissent states that we assume that a first Paragraph IV ANDA filer who unreasonably delays in marketing its drug cannot lose its right to exclusivity. The dissent is incorrect. Our conclusion that the first filer in this case, i.e. Ivax, cannot forfeit its exclusivity period is not based on an assumption, but rather the texts of the Hatch-Waxman Act and the MMA. *See* discussion *supra* note 2. As discussed, the MMA amendments to the Hatch-Waxman Act include a grandfather provision that specifically exempts a certain class of Paragraph IV ANDA filers, including Ivax, from being subject to the MMA's 180-day exclusivity forfeiture provisions. Accordingly, it cannot plausibly be argued that Ivax may nevertheless forfeit its exclusivity period.

Third, the dissent states that our analysis "assumes that [Caraco] will prevail in its non-infringement claim – an uncertain assumption at best." We make no such assumption, nor need we. A plaintiff need not prove it will prevail on the merits of its case in order to prove that it has standing to bring the case. *Steel Co.*, 523 U.S. at 89 ("It is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the courts' statutory or constitutional power to adjudicate the case.").

creates a potential for lost profits. Accordingly, Caraco's action is ripe for judicial review.

C. Mootness

The mootness doctrine requires that the requisite personal stake that is required for a party to have standing at the outset of an action must continue to exist throughout all stages of the action. *Geraghty*, 445 U.S. at 397, 100 S. Ct. 1202. The Supreme Court has articulated the mootness standard as follows:

> Simply stated, a case is moot when the issues presented are no longer "live" or the parties lack a legally cognizable interest in the outcome. Where one of the several issues presented becomes moot, the remaining live issues supply the constitutional requirement of a case or controversy.

Powell v. McCormack, 395 U.S. 486, 496-97, 89 S. Ct. 1944, 23 L. Ed. 2d 491 (1969) (internal citations omitted). The question here is whether Forest's unilateral covenant not to sue Caraco on the '941 patent renders Caraco's declaratory judgment action moot.

To be sure, Forest's covenant not to sue eliminates any reasonable apprehension of suit on the '941 patent. If a threat of suit was the only action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case and divest the district court of Article III jurisdiction. *See, e.g.*, *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058-59 (Fed. Cir. 1995). *But see Fort*

James Corp. v. Solo Cup Co., 412 F.3d 1340, 1347-49 (Fed. Cir. 2005) (holding that a patentee's covenant not to sue an alleged infringer after a jury verdict of noninfringement did not moot the alleged infringer's counterclaim for unenforceability). However, Caraco does not only allege that it has a reasonable apprehension of suit on the '941 patent. Caraco also alleges that the listing of the '941 patent in the Orange Book effectively prevents Caraco from entering the drug market. Essentially, Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context.

Clearly, in the ordinary infringement context, even when a patentee maintains that its patents are valid and infringed by a potential defendant, a covenant not to sue allows the recipient to enter the marketplace. Indeed, a covenant not to sue on a patent ensures that the covenant's recipient will not be liable for damages or subject to an injunction for infringement of that patent. However, in the Hatch-Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval. Moreover, an NDA holder's covenant not to sue a subsequent Paragraph IV ANDA filer does not affect the FDA's authority to approve the ANDA. As discussed above, where the first Paragraph IV ANDA filer fails to trigger its own exclusivity period, a subsequent Paragraph IV ANDA filer can only obtain FDA approval before the relevant Orange-Book-listed patents expire by obtaining a judgment that those patents are invalid or not infringed. Such a judgment is required to trigger the first Paragraph IV ANDA filer's exclusivity period and thus allow the FDA to approve the subsequent Paragraph IV ANDA 181

days after the triggering event. Under these circumstances, even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771.

Here, Forest's covenant not to sue Caraco does not allow Caraco to enter the generic drug market. Only by obtaining a judgment of noninfringement on both the '712 and '941 patents can Caraco trigger Ivax's 180-day exclusivity period, which currently prevents the FDA from approving Caraco's ANDA. Without a judgment of noninfringement on the '941 patent, even if Caraco prevailed against Forest in the separate infringement action on the '712 patent, Caraco would not be able to activate Ivax's exclusivity period via the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Moreover, until Ivax's exclusivity period expires, the FDA cannot approve Caraco's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Thus, terminating this action without a judgment with respect to infringement on the '941 patent could delay FDA approval of Caraco's ANDA and thereby exclude Caraco from the drug market, even if its generic drug does not infringe the '941 patent. In these circumstances, Forest's covenant not to sue Caraco does not eliminate the controversy between the parties.

In sum, Caraco's declaratory judgment action presents an Article III controversy as to whether the drug described in Caraco's ANDA infringes Forest's

Orange-Book-listed '941 patent. This controversy is not premised only upon a threat of an infringement suit. A controversy also exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market. Forest's covenant not to sue does not eliminate the controversy with Caraco, because the controversy can only be resolved by a judgment that determines whether Forest's '941 patent is infringed by the drug described in Caraco's ANDA. Accordingly, we hold that this action presents an ongoing Article III case and controversy.

IV. CONCLUSION

For the foregoing reasons, we reverse the district court's decision dismissing Caraco's declaratory judgment action and remand for further consideration.

REVERSED AND *REMANDED*

FRIEDMAN, Senior Circuit Judge, dissenting.

I would affirm.

I

A. In most instances an alleged infringer seeks a declaratory judgment of non-infringement or patent invalidity to protect itself from a subsequent judicial determination that has a significant adverse financial impact upon the infringer. The present case involves no such danger or possibility, since the covenant not to sue precludes Forest (the proprietary manufacturer) from subjecting Caraco (the generic manufacturer) to damages for infringement of the '941 patent.

Here Caraco's reason for seeking a declaratory judgment of non-infringement is quite different. Its concern is not that it may be sued for infringement if it markets its generic version of the patented drug, but that unless it can obtain a present judicial determination of that issue, its ability to enter the market may be delayed. This claim stems from and is based upon the particular provisions of the Hatch-Waxman Act.

Under that Act someone seeking to market a generic version of a patented drug files an Abbreviated New Drug Application (known as an "ANDA"). The filing of an ANDA constitutes an act of infringement. If, within forty-five days of receiving a notice of such filing that alleges that the patent on the drug is invalid or that the proposed generic drug does not infringe the patent, the proprietary manufacturer sues the generic

manufacturer for infringement, the Food and Drug Administration cannot approve the ANDA for thirty months. The Act also provides that the first generic manufacturer to file an ANDA covering the patented drug has the exclusive right to sell such generic product for 180 days following the first sale of the generic product or a court decision holding the patent invalid or not infringed. This provision, under which the 180-day period of exclusivity is triggered by a judicial decision holding the patent invalid or not infringed, is the basis for Caraco's contention that there was an actual case or controversy before the district court despite Forest's covenant not to sue for infringement.

The theory, as I understand it and as the court apparently views it, is that the other generic manufacturers who filed first might not begin to sell their generic product upon either the expiration of the thirty month stay period or of the patents, and because the generic manufacturers cannot begin selling their products until 180 days after the first-filing generic manufacturer begins its sales, the result of such earlier filing by the generic manufacturer may be to delay Caraco's ability to begin marketing its product for a substantial period, or even indefinitely. Caraco thus contends, and the court holds, that it should be able to invoke the alternative statutory triggering mechanism for the 180-day exclusivity period—a judicial determination of patent non-infringement or invalidity—by maintaining its declaratory-judgment litigation.

This argument is highly speculative and conjectural, and involves uncertain legal issues that have not yet been resolved.

I have no basis for concluding that the first-filing generic manufacturer will, or is likely to, delay bringing its product to market after the '712 patent expires. Indeed, such delay would seem inconsistent with that manufacturer's being the first to file its ANDA—a situation it presumably sought to give it the competitive advantage of having the exclusive right to sell its generic products for the first 180-days after that product went on the market.

The argument also assumes that the 180-day exclusivity period would not begin to run until the generic manufacturer actually begins marketing its product, and any delay in such marketing will simply defer the beginning of the 180-day period. It could plausibly be argued, however, that despite the seemingly absolute nature of the statutory 180-day exclusivity, a generic manufacturer that unreasonably delays the commencement of marketing after the thirty month period and the patent term have expired, loses its right to exclusivity. Indeed, although the issue has not been raised in this appeal, it could be argued that the thirty month period itself terminates if, after triggering that period by suing the generic manufacturer for infringement after it files its ANDA, the proprietary manufacturer in effect vitiates such action by executing a covenant not to sue for infringement and dismissing its infringement suit.

Finally, Caraco's argument assumes that it will prevail in its non-infringement claim—an uncertain assumption at best.

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S. Ct. 764, 771, 166 L. Ed. 2d 604 (2007),

the Supreme Court recently stated that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Considering all the circumstances here, I answer that question negatively.

B. The court twice cites the legislative history of the Hatch-Waxman Act. The "history" that it cites, however, consists exclusively of statements during the debate on the legislation made by Senator Kennedy, whom it describes as the "ranking member" of the Senate committee.

Senator Kennedy, however, was not a sponsor of the legislation. There is no indication that his statements reflected the views of the majority of the committee or of the Senate, or the sponsors of the legislation. In my view, Senator Kennedy's statements do not provide an appropriate or adequate basis for determining the scope and meaning of this legislation. *See Garcia v. United States*, 469 U.S. 70, 76, 105 S. Ct. 479, 83 L. Ed. 2d 472 (1984) ("In surveying legislative history we have repeatedly stated that the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill, which 'represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.' We have eschewed reliance on the passing comments of one Member, and casual statements from the floor debates." (citations omitted)).

If, however, Senator Kennedy's comments are an appropriate source for determining the meaning of the statute, I would give considerable weight to his statement quoted in footnote 14 of the court's opinion, that: "We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe." I do not agree with the court that this statement "only emphasize[s] Congress's intent that that jurisdiction of federal courts to resolve CAPCs would extend to the limits of the Constitution."

C. The court contends that its decision is appropriate and necessary to avoid a defeat of the objectives Congress sought to achieve in the Hatch-Waxman Act that, it concludes, would result from permitting a proprietary manufacturer to use covenants not to sue to preclude generic manufacturers from obtaining declaratory judgments on patent infringement and validity. To the extent that Congress may conclude that particular judicial interpretations of the Act thwart the purposes of the legislation, it is for Congress, not for this court, to make whatever changes in the Act it deems appropriate.

II

Although I disagree with the court's substantive rulings, I agree with the court's apparent rejection of Forest's contention that Caraco's appeal was frivolous and seeking sanctions of therefor. The appeal presents important questions under the Hatch-Waxman Act that this court has not

previously decided. Under no circumstances could the appeal fairly be characterized as frivolous. Indeed, it is difficult to see how an appeal in which the appellant prevails and the appellate court adopts its contentions could be so described.

Perhaps Forest made the frivolity contention under the misguided belief that by doing so it was enhancing its prospects of success on the merits. If that was its view, it was sadly mistaken. In making the frivolity argument, which occupied five pages of its brief, Forest's counsel was neither helping his client's case nor aiding the court in performing its appellate function. In my view, a lawyer who makes such a contention of frivolity—and at the close of his oral argument, Forest's counsel stated he continued to characterize this appeal as frivolous—engages in sanctionable conduct.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2007-1404

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Plaintiff-Appellant,

versus

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S.

Defendants-Appellees,

Appeal from the United States District Court for the Eastern District of Michigan in Case No. 07-CV-10737, Chief Judge Bernard A. Friedman.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellees,* and a response thereto having been invited by the court and filed by the Appellant, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

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* Amici curiae, Pfizer Inc.; Washington Legal Foundation; Merck & Co., Inc.; Pharmaceutical Research and Manufacturers of America, et al.; and Ivax Pharmaceuticals, Inc. were granted leave to file briefs in support of the Appellees combined petition for panel rehearing and for rehearing en banc.

The mandate of the court will issue on July 1, 2008.

FOR THE COURT,

/s/Jan Horbaly/JB
Jan Horbaly
Clerk

Dated: 06/24/08

cc: James F. Hurst
Gerald J. Flattmann, Jr.
All Amici

CARACO PHARMA V FOREST LABS, 2007-1404
(DCT - 07-cv-10737)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff,

Civil Action No. 07-CV-10737-DT

vs.

FOREST LABORATORIES, INC., et al.,
Defendants,

HON. BERNARD A. FRIEDMAN

_____/

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION (DKT. NO. 8)

On May 30, 2007, this matter came before the Court on Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction. A hearing was held and oral argument heard. For the reasons stated on the record,

IT IS ORDERED that Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction is granted.

IT IS FURTHER ORDERED that Plaintiff's Complaint is dismissed.

/s/Bernard A. Friedman
BERNARD A. FRIEDMAN
CHIEF UNITED STATES DISTRICT JUDGE

Dated: May 31, 2007
Detroit, Michigan

I hereby certify that a copy of the foregoing document was served upon counsel of record by electronic and/or first-class mail.

/s/Carol Mullins
Case Manager to Chief Judge Friedman

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

CARACO PHARMACEUTICAL

LABORATORIES, LTD.,

Plaintiff,

Case Number:

–v–

07–10737

FOREST LABORATORIES,

INC., et al.,

Defendants,

_____/

DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

BEFORE THE HONORABLE

BERNARD A. FRIEDMAN

UNITED STATES DISTRICT JUDGE

238 U. S. Courthouse & Federal Building

231 West Lafayette Boulevard West

Detroit, Michigan 48226

WEDNESDAY, MAY 30TH, 2007

APPEARANCES:

For the Plaintiff: Derek Sarafa, Esq.
Raymond Ruthledge [*sic*], Esq.

For the Defendants: Gerald J. Flattmann, Esq.

Court Reporter : Joan L. Morgan, CSR
Official Court Reporter

Proceedings recorded by mechanical stenography.
Transcript produced by computer-assisted transcription.

Detroit, Michigan

Wednesday, May 30th, 2007

-- --- --

THE CLERK: Calling Caraco Pharmaceutical Laboratories versus Forest Laboratories, case number 07-10737.

THE COURT: Good afternoon.

MR. SARAFA: Judge, a little housekeeping before we go to the case.

THE COURT: Housekeeping.

MR. SARAFA: My colleague, Sam Park, whom I have known, four or five years, he would be a tribute to the Bar here in the Eastern District of Michigan. I'd like to take this opportunity to move his admission.

(Attorney Admission, not on record.)

THE COURT: Appearances.

MR. FLATTMANN: Your, Honor, good afternoon.

Gerald Flattmann, from Kirkland & Ellis, for the defendants in case, Forest and Lundbeck. With me are my colleague, Christine Woogis [*sic*] (ph.), Mr. Ron King from the Clark Hill firm. Also from Forest Laboratories, Eric Bagadino [*sic*] (ph.) as patent counsel.

THE COURT: Thank you.

MR. BOLTON: Jordan Bolton from Clark Hill.

MR. SARAFA: Derek Sarafa, for Caraco Pharmaceutical. With me is my colleague, Sam Park, Ray Ruthledge [*sic*], local counsel. Also the general counsel of Caraco, Steven Walker.

THE COURT: Okay. Defendants' Motion.

MR. FLATTMANN: Thank you, your Honor.

Your Honor, this is a Motion to Dismiss for lack of subject matter jurisdiction, and we are the declaratory judgment defendant in this particular case.

Your Honor, the motion before you I would submit presents a question that's actually a pretty simple one on the facts that are raised by Caraco's declaratory judgment complaint. It's a question of whether that complaint alleges case or controversy between the parties under Article III of the Constitution. Or, it's really asking you to issue an impermissible advisory opinion.

Here, the facts are clear that Caraco is seeking an impermissible advisory opinion on a moot question. And it's doing that as a means to an end. You know, we talked about the Hatch-Waxman framework report, and one of the most important parts of that Hatch-Waxman framework is the 180 days of exclusivity that's given to the generic filer that decides to take the first risk in challenging a patent and becomes the first filer of an ANDA, an Abbreviated New Drug Application.

Caraco was not that party here. That party was Ivax Pharmaceuticals which did take that risk with regard to both the '712 patent which is before you in another case, and on the '941 patent that we're discussing today.

Now, that wasn't an Ivax exclusivity, it's Ivax's and Ivax's alone. And what Caraco is trying to do with this declaratory judgment complaint is to

trigger Ivax's 180 days. One of the ways it can trigger that is through a judgment of non-infringing. That's one of the many ways that it can be done. And they're looking to do that here in order to sort of make an end —

THE COURT: What's your — your real bottom line is covenant not to sue.

MR. FLATTMANN: That's right, your Honor.

THE COURT: And you haven't done it, and you have 13 or 14 others and you haven't done it there. The real bottom line is there's no controversy.

MR. FLATTMANN: There's no controversy here.

THE COURT: Is that your bottom line?

MR. FLATTMANN: That's my bottom line.

THE COURT: Okay.

MR. FLATTMANN: There's one count in the complaint, your Honor. It's a declaratory judgment of a non-infringement claim.

THE COURT: On the '941.

MR. FLATTMANN: Of the '941.

THE COURT: And you've had 14 or 13 other people that are doing the same thing and you haven't sued them.

MR. FLATTMANN: I haven't sued them.

THE COURT: Any indication you're going to sue these folks?

MR. FLATTMANN: Well, we can't sue them. We just gave them a covenant not to sue which forever estops us.

THE COURT: Isn't that your best shot? That's what the bottom line is —

MR. FLATTMANN: It's simple. That's all there is to it.

THE COURT: That's how I see it.

MR. FLATTMANN: And they're asking for an advisory opinion. And I could go on and tell you about the Supreme Court cases that have come down that they've tried to use to sort of leverage or bootstrap themselves into future customers here, but the fact remains there's only claim in their DJ complaint and it's gone, it's mooted.

THE COURT: Okay.

MR. FLATTMANN: Okay.

THE COURT: I want to see the chart.

MR. SARAFA: Judge, the covenant not to sue absolutely does not resolve the controversy, okay, and it's absolutely clear in Novartis and it's clear in MedImmune, the only way you could rule in their favor on the point, your Honor, is if you ignored those two decisions, period .

THE COURT: Doesn't it differentiate —

MR. SARAFA: No, it can't and I'll tell you why. It's very simple.

Here is the language from the Novartis decision. There's no question — there's no question in binding authority, your Honor. There's no question — this is just the language from the case, your Honor. There's no question —

THE COURT: Oh, you want me to read it. Okay.

MR. SARAFA: There's no question binding authority, your Honor. There's no question it is identical in every respect, they agree, with the exception of the covenant not to sue —

THE COURT: With the exception of the covenant not to sue.

MR. SARAFA: Your Honor, look at the language of the case. Now, the case considered five factors, five factors, okay? Here's what it says in three of them.

> "A justiciable declaratory judgment controversy arises for an ANDA filer when (1) a patentee lists patents in the Orange Book . . ."
>
> That's undisputed, that's the case here.

"(2) The ANDA applicant files its ANDA certifying the listed patents under paragraph IV . . ."

No dispute.

"(3) The patentee brings an action against the submitted ANDA on one or more of the patents . . ."

No dispute.

And then the case says,

"The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents."

Your Honor, that ends the inquiry.

THE COURT: Whoa, Whoa. Go back to three for a second.

MR. SARAFA: Three.

THE COURT: "The patentee brings an action against the submitted ANDA . . ."

MR. SARAFA: And there's no dispute on that.

THE COURT: ". . . on one or more of the patents."

MR. SARAFA: Yes, they agree. They've done it. They've sued on the '712. They have brought an action.

Your Honor, there's no dispute. You can ask Mr. Flattmann, right now —

THE COURT: Go on.

MR. SARAFA: There's no dispute.

Judge, dispositive. Dispositive means that's the end of the inquiry. Now, your Honor, this was not a case where the Court didn't consider the possibility of a covenant not to sue. There were two other circumstances the Court considered. One was the legislative history, and the other was the existence or non-existence of a covenant not to sue. Here's what the Court said as to that. It didn't say it was dispositive, Judge. It said, that a covenant not to sue is a fifth circumstance contributing to a finding that Teva has the justiciable declaratory judgment controversy. Contributed.

And in the same opinion it tells you that these three factors are dispositive, Judge. It can't be any clearer than that. Cannot be any clearer than that. The decision — your Honor has obviously read the decision and I encourage you to read it again, your Honor. There are no two ways about it. The decision did not hinge on the existence or non-existence of a covenant not to sue.

And what is more, your Honor, it couldn't possibly because the Supreme Court in MedImmune just rejected the exact argument that they're making here, the exact argument in the MedImmune decision that's only a few months old, Judge.

What happened in that case was the party that brought the declaratory judgment action had a fully paid up license. Now in the law and there's case law on this, a paid up license is the same as a covenant not to sue. Same thing. Same thing. Case law is clear on this point. We get a license, you're saying you don't sue me and I give you money. It's the same thing as a covenant not to sue.

The declaratory judgment defendant or the patent holder in that case could not have brought a cause of action. There was no underlying cause of action that they could have brought against the licensee. It was impossible.

In fact, the Supreme Court said quite clearly that the risk of being sued was, and I quote, "At least remote, if not, is non-existent." As long as those payments are made there is no risk that respondents will seek to enjoin petitioner. Yet, the Supreme Court went on to say, there was still a controversy in a case that is basically a covenant not to sue, the effective equivalent of a covenant not to sue. The Court recognized jurisdiction can exist, "even though the very reason the plaintiff sought declaratory relief was that the defendant had given no indication he would file suit."

So, Judge, respectfully, the covenant not to sue is not the Novartis decision which is binding on your Honor, did hinge upon it. The idea that a covenant can moot the controversy has been rejected by the MedImmune Court and, more importantly, Judge, it doesn't remove the controversy. The Novartis decision was very clear. The controversy is just not infringement or non-infringement. The controversy

is whether or not our ANDA can be approved so we can sell a generic version of our drug — a generic version of Lexapro.

And the opinion in Novartis was exceedingly clear on that point. Here's what they said. Here's what the Novartis court said — he's trying to make it out to be a situation where there's just one case and there's one count, but that argument was expressly made and rejected in Novartis. Here's what Novartis, Judge.

THE COURT: Tell me where you're reading, because I'm reading the section — I've got the case right here.

MR. SARAFA: Okay. I don't know which version your Honor as, but —

THE COURT: I have the West law —

MR. SARAFA: Okay.

THE COURT: Just tell me where it is.

MR. SARAFA: Judge, if you look under head note 2223.

THE COURT: Which version do you have?

MR. SARAFA: I have — I think it's West law.

THE COURT: What page?

MR. SARAFA: On mine, it's page 11.

THE COURT: Okay.

MR. SARAFA: On the left-hand column.

I want to be clear on this, Judge, what they're saying is, there's one count, and that count is mooted by a covenant. And what the Novartis court specifically explained it, you don't look at it like that, that's not the controversy. The controversy is both cases. The controversy is getting our ANDA approved. Here's what the Court said,

"While it is true that the suit on the 937" —

THE COURT: You're reading where? The middle of page 11?

MR. SARAFA: Middle of the way down on the left-hand column, starting with "While."

THE COURT: Okay starting with —

MR. SARAFA: "While it is true . . ."

THE COURT: Okay, give it to me.

MR. SARAFA: Here's what it says,

> "While it is true, that the suit on the '937 patent is a different 'case' than Teva's declaratory judgment action . . ." same circumstance we have here.
>
> "Novartis created a present and actual 'controversy' by choosing to sue under 35 U.S.C. 271 (e) (2) (A) on Teva's single act of infringement, thereby placing into actual dispute of the soundness of Teva's ANDA, and Teva's ability to

> secure approval of the ANDA. Thus, while Teva's declaratory judgment action and the pending 937 suit are different 'cases' they arise from the same controversy created when Novartis listed its Famvir patents in the Orange Book. Teva submitted its ANDA certifying all five Famvir patents under paragraph IV, and Novartis sued Teva challenging the submission of Teva's ANDA."

Judge, this case came out two months ago. It's indisputably binding on your Honor, and what it said is the controversy is not infringement or non-infringement. The controversy is whether or not our ANDA can be approved. And that makes sense, Judge. The whole reason we have this lawsuit is so we can get onto the market with our generic version of the product. And then provide in the covenant not to sue, it doesn't eliminate that controversy it exacerbates it, Judge, it makes it worse because they know that if they do that, we can't get an order stating that we don't infringe. Judge, they admit we don't infringe the '941 patent. They've admitted it. All we need is an order from your Honor saying it's dismissed on that basis. If they have nothing to lose here, Judge, why are they fighting tooth and nail to get this dismissed on the basis of a lack of subject matter jurisdiction.

I urge you to ask Mr. Flattmann that same question because this could be over in about 20 seconds, Judge. I move for summary judgment, they don't resist, your Honor grants the order, they don't spend any expenses. If they don't have anything at

stake, Judge, why don't we do that and — if your Honor will just indulge me for a few minutes.

I tried for a security, Judge. It's somewhere it the range of 20 billion to 70 billion dollars. They say they don't have a horse in this race. Your Honor, it's just not true. It's just absolutely untrue. If they didn't have a horse in this race, if they didn't want to spend the money being, quote, unquote, dragged into pointless litigation, what they would do is provide us what we need, an order saying we don't infringe. Why are we doing it, Judge? Let me show you: the '712 patent which they have asserted against us expired in 2005. The '941 patent they agree we don't infringe, expires in 2023. The reality is, Judge, these ten years right here, we can't go to market because of this patent that they agree we don't infringe. And for them, this equates to about 70 million dollars because if there's generic competition during that time, Judge, what that means is they will lose 80 to 90 percent of their revenues, their revenues are about 5 to 60 billion dollars a year. It's about 70 billion.

Now, Judge, if Ivax loses their case on the '712 patent, they lose that exclusivity. And what that should mean for us is if we win on the '712 patent which is the only patent they claim we infringed, we ought to be able to market. So what are they doing here? They're using this patent and by not asserting it, they are getting the benefit of a monopoly protection anywhere in the range from an additional 10 to 15 years.

Now, it's possible, it's possible that Ivax could launch after the expiration of the '712 patent, and

we would launch six months after that. But what does that mean, Judge? That means we win tomorrow on the '712 patent. We win tomorrow on the only patent they're asserting against us. We still can't go to market. We still can't go to market because of this unasserted patent.

And, Judge, this is something of their own making. They listed the patent in the Orange Book. They took the statutory protection of the Hatch-Waxman Act including the 30-month stay and everything else that goes with it —

THE COURT: Tell me why you can't go to market.

MR. SARAFA: Very simple, Judge. We can't go to market until 180 days after the expiration of Ivax's exclusivity. And what that means is if Ivax wins their suit, good for them. More power to them. They get that exclusivity —

THE COURT: For a 180 days.

MR. SARAFA: They're making it sound like we're doing something improper, we're not.

THE COURT : Okay.

MR. SARAFA: If they win, they get it.

THE COURT: Okay, what if they don't get it?

MR. SARAFA: They've already lost, okay, so — and if they lose on appeal, then the '712 is not — it doesn't impair us.

THE COURT: Right.

MR. SARAFA: Okay.

THE COURT: Why does the '941 —

MR. SARAFA: Because they have exclusivity on both. They have exclusivity on the '941 and the '712. But, Judge, why would they get the benefit of the — why would they get the benefit of the exclusivity on the '941? They can't even come to market because the '712 is locked.

THE COURT: And they get exclusivity on the '941 why?

MR. SARAFA: Because they were the first to file on that.

THE COURT: Do they get that forever or just for the 180 days?

MR. SARAFA: The 180 days. So what that means, Judge, is because of this patent, which they agree we don't infringe, we can't launch for 180 days after the expiration of that patent, we're in 2023

Judge, please —

THE COURT: Well, wait. Even today since you don't infringe if you want to do it and you have the authority to do it, you could do it.

MR. SARAFA: No, we couldn't.

THE COURT: Why not?

MR. SARAFA: We can't do it because the way — because we're barred by law. The FDA cannot approve our ANDA under those circumstances.

THE COURT: All right.

MR. SARAFA: Judge, why should they be entitled to a monopoly profit to billions of dollars —

THE COURT: That's not the issue. The issue is not —

MR. SARAFA: Okay. Why should we be harmed to the tune of tens of millions of dollars or hundreds of millions of dollars —

THE COURT: Still not the issue. Why do I have jurisdiction? It's not an equity.

MR. SARAFA: Very simple, Judge. You have jurisdiction because the fact that their listing of this in the Orange Book, and they're invoking the statutory protection and the benefits they weep from the statutory protection means that there is a controversy here. The fact that we can make of hundreds of millions and make them lose billions is better evidence of that — of the existence of that controversy. Judge, if this is not a controversy it must be the biggest non-controversy in the history of mankind.

THE COURT: You have the case — look on the page. Is your 19 pages?

MR. SARAFA: Let me see. Of course, not, it's 16 pages.

But why don't you give me a head note number, the little note.

THE COURT: It's —

MR. SARAFA: If you tell me the passage, I may know it.

THE COURT: The passage is,

> "We believe that the only circumstance in which a case of controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe."

MR. SARAFA: Yes, does not — does not remotely affect your Honor's opinion in this case.

THE COURT: Tell me why.

MR. SARAFA: For several reasons, Judge. Number one, it says "might." Not exactly a resounding — it's from legislative history and it says "might." The reason it says "might" is because it probably doesn't know about all the possible circumstances that could arise.

The second point, Judge, this was pre-MedImmune, preNovartis decision. This is based on the existence of the quote, unquote, reasonable apprehension test. When you're dealing with reasonable apprehension, that makes sense. There

can't be a reasonable apprehension if there's a covenant not to sue.

But, Judge, MedImmune changed that dramatically. It explicitly threw out reasonable apprehension, threw it out, it's gone, and took a much broader all of the circumstance approach. Why did it do that? Because it was presented to the case just like the one here. There was license which was effectively a covenant not to sue. But, Judge, there was a controversy underneath, and it broadened it and said you have to be broader than reasonable apprehension. You have to have all the circumstances.

THE COURT: If you're not violating the '941 patent, what kind of declaratory relief do you want —

MR. SARAFA: Very simple, Judge. All we need is an order saying the case is dismissed because we do not infringe the '941 patent. And since they agree that we don't, it should be pretty easy to do. I think it would take about 30 seconds, at the most —

THE COURT: What would that do for you?

MR. SARAFA: What that does, is that — this exclusivity that otherwise would exist, it triggers it. It starts running and it basically moots it out. So it doesn't prevent us from going onto the market.

Now, Judge, that exclusivity is borne out of their action.

THE COURT: In the covenant not to sue, that wouldn't give it back to you?

MR. SARAFA: Of course not. That's why they did it that way. That's exactly why they did it. That's why even though they admit —

THE COURT: But they're entitled to do it that way.

MR. SARAFA: No, no, they're not. They can do it that way, but it still leads to controversy. The controversy, Judge, is whether or not we can get to market. That's what this whole — the Hatch-Waxman Act is about. It's generic competition to the market sooner. It's to get you heads up or down on whether you're likely to infringe the patent.

And what they're doing — and, actually, Judge, they're not letting us get that. The existence of the covenant says you can't get a fair adjudication of whether or not you infringed. This whole reason they're doing it; that way, Judge, is to prevent a decision on the merits. They admit we don't infringe. They're not going to resist non-infringement. They made it very clear. So why shouldn't we get the decision on the merits?

Judge, they put this patent in the Orange Book. When they do that, they say to the world, this protects our drug. They get all the benefits that come with that.

The Novartis case is very clear. It said you cannot simultaneously leverage the benefits of the Act and shrink from your responsibilities.

THE COURT: I've got you now. You've convinced me. Let me go back to the other side. Let's see if you can re-convince me.

MR. FLATTMANN: Okay. Your Honor, Novartis and MedImmune did not change the basic constitutional rule that you need to have a case of controversy and that you can't make an advisory opinion. I'd like to —

THE COURT: But isn't there a controversy here?

MR. FLATTMANN: There's no controversy here.

THE COURT: There's no controversy because you agreed that the '941 does not infringe.

MR. FLATTMANN: No, your Honor. There is no controversy because we gave a covenant not to sue.

THE COURT: Assume you believe the '941 is infringed.

MR. FLATTMANN: Your Honor, I don't know the answer to that question.

THE COURT: That's fair.

MR. FLATTMANN: And would never admit it or said anything like what counsel said concerning infringement.

THE COURT: Let me ask you this

MR. FLATTMANN: Yes, your Honor.

THE COURT: Do you agree with his analysis that if the '941 is not infringed then the 180 days will not apply to them?

MR. FLATTMANN: I don't necessarily agree with that.

THE COURT: Tell me why.

MR. FLATTMANN: A 180 days is applicable to the '712 patent as well. Ivax had full exclusivity on those patents. What counsel explained to you was one of many possible computations that could result in a situation that he mentioned —

THE COURT: Is that one of them?

MR. FLATTMANN: That is one of —

THE COURT: Assuming the '712, the — the suit is over in a 180 days, do you believe they have to wait another 180 days on the '941?

MR. FLATTMANN: I don't know. I think that's somewhat vague part of the law. There's one decision out of the D. C. Circuit that they cite —

THE COURT: Certainly your company could take the position they don't have more competition that they have to wait a 180 days. It's a good decision for you, for your company.

MR. FLATTMANN: Well, it's a good decision I think for Ivax. Whether it's a good decision for us — it could be an irrelevant decision for us depending on whether Ivax —

THE COURT: Assuming it is on the market —

MR. FLATTMANN: One generic is on the market the prices erode and the market is essentially gone.

THE COURT: But it's still a determent [*sic*] to them if they have to wait a 180 days.

MR. FLATTMANN: It could be, your Honor. But that's an economic interest. It's not a legal interest, and it's not a case of controversy under the constitution.

What they're asking for is, is sort of an observant result. They're asking you to decide whether the '941 patent is infringed when I've already given them a covenant, my client has already given them a covenant never to sue to infringement.

THE COURT: Have you given anyone else —

MR. FLATTMANN: I'm sorry, your Honor?

THE COURT: Have you given anybody else one of them or are you prepared to do so?

MR. FLATTMANN: No, we haven't encountered any of those situations with the '941 patent.

THE COURT: Why did you put it in the Orange Book?

MR. FLATTMANN: Because we're required to do so by law and because it covers our product. Any composition of the patent it covers, it must be listed in the Orange Book.

But, your Honor, their economic interest, their economic complaint which is by the way speculative, it depends on one possible scenario, one possibility. It's what they pledged in their complaint. It's not what they're asking you to do.

Their beef is with Congress about what they perceived to be the inequities of a 180 days with specific rules and with the impact that it has on them as a second or third filer.

It's not a controversy as the Maryland Casualty case put it between two parties having adverse legal interest in this action. There's only one count as you said — as I said at the very beginning of this argument. That count is gone because of our covenant not to sue.

A consent judgment would be inappropriate at this point and would also lack jurisdiction now with the covenant not to sue is in place.

The cases that he cites to you don't stand for the proposition that he mentioned. They don't get rid of the rule that you cannot decide an abstract question, give an advisory opinion on something that's already done, namely infringement.

The Novartis case clearly noted that there was no covenant not to sue. And that case places discussion and dispositive factors which counsel mentioned to you under the Rubric Patent Uncertainty. It discussed the fact that given that patents are out there which are unasserted, and could be asserted at a later date, combined with these factors, in that context those factors are

dispositive. But in Novartis, there was no covenant not to sue.

In MedImmune there was no covenant not to sue. In that case, the Supreme Court noted right up front in the syllabus that the petitioner considers a letter from Genentech a clear threat to enforce the patent, terminate the license, and bring a patent infringement action if petitioner did not pay.

I can't do that. My client can't do that. We're forever estopped from asserting infringement of these — this patent against Caraco for — and their products. And that means there's no case of controversy before you.

So MedImmune and Novartis are entirely distinguishable. The court had it right in its opinion, the First District Court opinion to deal with Novartis, MedImmune and covenant not to sue.

And what the defendants are really looking for is a means to an end. They want to use the federal judiciary machinery as a means to an end triggering the exclusivity of the parties and the parties to the facts, your Honor.

So I submit that their beef is with Congress. Their dispute is with Congress. Maybe with the first filer, maybe with the FDA, but it's not with us, at least not as pled in this particular complaint.

And every case that has looked at, every court that has looked at a covenant not to sue in a patent infringement action and we've cited several in our brief, the Microchip case, the Amana case, the Super

Sack case, the Intellectual Property Development case, and lastly the court's decision in Merck v Apotex, which is on all fours. Every one of those found that the infringement claim as to that patent was moot, and that the court was being called upon to issue an impermissible advisory opinion which if we looked at the obserbia [*sic*] (ph) you'd be asked — I'd be asked to put on the proofs of infringement. I'd have to seek through discovery whether or not they infringed, and I'd have to prove that to you even though I'm estopped from asserting infringement against them. They, on the other hand, would be proving that they don't infringe even though I promised never to sue them for infringement. That's a classic, classic advisory opinion on an abstract question of law. And their economic interest cannot create a legal interest under the pleading here.

THE COURT: Okay. I'll give you another minute and a half or two minutes.

MR. SARAFA: Thank you, Judge, very briefly.

The Novartis decision was very clear, this is not an economic interest. Here's what it said, Judge, here's what it said.

> "Novartis' selective 937 suit" — they have a selected suit — "creates uncertainty as to Teva's legal rights under its ANDA. Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer in Teva's situation is not

> legally free to enter the market because federal statutes prohibit it. Hence, Teva suffers a direct legal injury from the actions that Novartis has already taken-Novartis' listing of the five Famvier patents int eh [*sic*] Orange Book and Novartis' suit against Teva challenging the validity of Teva's ANDA which requires judicial relief."

Judge, bottom line, he didn't deny it and he also didn't answer my question —

THE COURT: What do you think of Judge Sleet's (ph) opinion?

MR. SARAFA: I don't think it's worth the paper it's written on —

THE COURT: Oh, oh —

MR. SARAFA: Sorry, Judge —

THE COURT: Good thing I don't know him.

MR. SARAFA: Judge, with all due respect to Judge Sleet —

THE COURT: I'm teasing you.

MR. SARAFA: He doesn't cite — he doesn't cite this is a Dispositive test.

And I didn't hear Mr. Flattmann contest that the word "Dispositive" is right here, or that it is actually dispositive. The reality is, Judge, there's a bottom line here. The bottom line is we cannot get onto the

market until we get this order. The bottom line is what they've done is tantamount to an agreement that we don't infringe, and we can't even get to market without that order.

What I didn't hear him explain is why they won't just give us that order, Judge. And it's because they have so much at stake. It proves there's a controversy. I started off my argument saying give us the order saying we don't infringe if you don't have a horse in this race. He didn't even respond to that point, and it was the first thing that I mentioned. We are blocked from the market unless we receive this court order. There's only one place we can get it. It's from your Honor, and there is no reason in the world why we should be kept off the market by a patent which they agree we don't infringe. And they say, well, we didn't agree. It's tantamount to an agreement, Judge. This is a company that if there was the slightest possibility that that patent could cover us, they would have sued us in a heart beat. They agree, and they have no defense to it.

The reality is, this is not something that Ivax or the FDA caused. As stated in the Novartis opinion, when you put a patent in the Orange Book, when you take the statutory protections, when you invoke those protections and you rely on them to keep your monopoly you have certain responsibilities. You can't leverage the benefits of the act and then ignore your responsibilities. They have to allow us to get a decision up or down on the merits of the patent. That is what is required to resolve this controversy, your Honor.

Thank you.

THE COURT: Thank you.

MR. FLATTMANN: I think he made a correct statement, we did not commit infringement and that's why the covenant not to sue.

THE COURT: Okay. In this matter —two great attorneys arguing. You had me going back and forth, and we've gone over this many times, Jeff and I, on the bench memo. I've read your cases.

The Court understands Caraco's motion — argument and it's very persuasive in terms of the economics and the business in terms of the statutory scheme. However, the Court can't — I agree with the defense, I think you have to look at Congress for that. I expected to see if there's a controversy. The Court doesn't believe that there's a controversy. I went back which I had not done before and looked at the complaint on page 19, and the complaint really is asking for the same relief as they already have. There's no controversy and that means that they have a covenant not to compete so that in effect I think I couldn't give anything advisory since they're not going to sue, there's no chance.

I'm not here just — this is, in effect, a DEC action as oppose to some kind of equitable action on whether or not the statute is fair and the 180 day rule and so forth, but there's no controversy. There's a covenant not to sue on the '941 so there's not going to be any loss, there's no threat of a lawsuit. There are others that are doing the same thing. There's no lawsuits. There could be, but it doesn't appear to be.

The defendants in this particular matter have made it clear that they intend to honor the covenant not to sue. It may be a technical way of getting around having their patent examined in this setting. I don't know about all settings, but I think they're entitled to that. It's part of the practice of law and the way that we handle things, but there's got to be controversy under Article III and there's no controversy and the Court should not be involved in it. Therefore, the Court will grant the motion.

Okay. Thank you.

(Proceedings concluded.)

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CERTIFICATE

I, JOAN L. MORGAN, Official Court Reporter for the United States District Court for the Eastern District of Michigan, appointed pursuant to the provisions of Title 28, United States Code, Section 753, do hereby certify that the foregoing proceedings were had in the within entitled l and number cause of the date hereinbefore set forth, and I do hereby certify that the foregoing transcript has been I prepared by me or under my direction.

_____

JOAN L. MORGAN,
CSR

Official Court Reporter

Detroit, Michigan
48226

Date:_____

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Plaintiff,

vs.

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD. and H. LUNDBECK A/S,

Defendants,

_____/

Case: 4:07-cv-10737
Assigned To: Gadola, Paul V
Referral Judge: Scheer, Donald A.
Filed: 02-20-2007 At 03:21 PM

COMPLAINT

Plaintiff Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), by its attorneys, for its Complaint against Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Defendants") alleges as follows:

INTRODUCTION

1. Caraco brings, and is entitled by statute to maintain, this action for declaratory judgment of patent non-infringement under, *inter alia*, the federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S. C. § 355 (j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as

amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Caraco's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Defendants' brand-name anti-depression medication LEXAPRO®, known generically as escitalopram oxalate.

3. Defendants purport to own U.S. Patent Nos. Rc. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). Upon submission by Defendants, the '712 and '941 patents were listed in FDA's compilation of approved drugs and their respective patents entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." As a consequence of such Orange Book listing, Defendants maintain, and have affirmatively represented to the world, that the '712 and '941 patents claim the approved drug LEXAPRO®, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Caraco, attempting to market a generic escitalopram product before expiration of the '712 and '941 patents.

4. Caraco seeks to market a generic escitalopram product before the expiration of the '712 and '941 patents. Therefore, as required by the FFDCA, Caraco has certified to FDA that its ANDA products will not infringe any valid or enforceable claims of the '712 and '941 patents and has further notified

Defendants of the legal and factual bases for those certifications. Caraco's submission of the so-called paragraph IV certifications to the '712 and '941 patents constitutes an artificial act of patent infringement putting Caraco at considerable risk of being sued by Defendants both before and after market entry.

5. This regulatory submission creates the necessary case or controversy and subject matter jurisdiction for Defendants to sue Caraco – and for Caraco to obtain declaratory judgment against Defendants – regarding infringement of the '712 and '941 patents.

6. In a separate lawsuit, *Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM), Defendants, in fact, sued Caraco for infringement of the '712 patent. Defendants, to date, have not sued Caraco for infringement of the '941 patent.

7. Caraco has satisfied all substantive requirements for approval of its ANDA, and is prepared to begin commercial marketing of its competing generic product prior to expiration of the '712 and '941 patents. But Caraco's approval has been delayed and Caraco is presently prevented from competing in the escitalopram market by purported generic marketing exclusivities arising out of the '712 and '941 patents. In *Forest Laboratories, Inc., et al. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143, Caraco is currently litigating and will obtain a court judgment as to the

validity, enforceability and/or infringement of the '712 patent. A declaratory judgment from this Court as to the '941 patent can alleviate Caraco's harm and allow Caraco to obtain approval of its product and compete in the lucrative escitalopram market.

8. In addition to a court order finding the '712 patent invalid and/or not infringed, unless Caraco obtains a similar court order on the '941 patent, Caraco faces potentially enormous infringement liability if it markets its generic product prior to expiration of the '941 parent. Only a declaratory judgment from this Court can alleviate this harm and allow Caraco to obtain approval of its product and compete in the escitalopram market free from such potential liability.

9. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Caraco and Defendants regarding the '941 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties. Caraco is entitled by law to bring and maintain this action for declaratory judgment of potent non-infringement under the Declaratory Judgment Act and the MMA where, as here, Defendants did not sue Caraco within 45 days of receipt of Caraco's notice of paragraph 1V certification to the '941 patent, and Caraco has offered Defendants an Offer of Confidential Access to Caraco's ANDA for generic escitalopram product.

10. Caraco is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Caraco's proposed generic escitalopram product does not and will not infringe

the '941 patent. Absent the exercise of jurisdiction by this Court and such declaratory relief, Caraco and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced generic escitalopram.

THE PARTIES

11. Plaintiff Caraco Pharmaceutical Laboratories, Ltd. is a Michigan corporation having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

12. Defendant Forest Laboratories. Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

13. Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

14. Defendant H. Lundbeck A/S is a Danish corporation having a principal place of business at Ottiliavej 9, DK-2500 Valby, Copenhagen, Denmark.

U.S. PATENT NO. 6,916,941

15. Upon information and belief, on July 12, 2005, the '941 patent, titled "Crystalline composition containing escitalopram" – a copy of which is attached hereto as Exhibit A – was issued to H. Lundbeck A/S as assignee.

16. Upon information and belief, the '941 patent is scheduled to expire on January 25, 2023.

17. Upon information and belief, H. Lundbeck A/S is the owner of the '941 patent.

18. Upon information and belief, Forest Laboratories Holdings, Ltd. is the exclusive licensee of the '941 patent and Forest Laboratories, Inc. holds New Drug Application ("NDA") No. 21323 on LEXAPRO® brand escitalopram oxalate tablet products.

19. Upon information and belief, Forest Laboratories Holdings, Ltd. has appointed Forest Laboratories, Inc. its exclusive distributor of LEXAPRO® brand escitalopram oxalate products in the United States.

20. Upon information and belief, Defendants have the right to sue for any infringement of the '941 patent.

JURISDICTION AND VENUE

21. Substantial, present, genuine and justiciable controversies exist between Defendants and Caraco regarding the '941 patent.

22. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271 (e)(5)).

23. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*; under the Declaratory Judgment

Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the '941 patent; and under the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. §§ 271(e)(5)), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

24. This Court can and should declare the rights and legal relations of the parties regarding the '941 patent pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

25. Caraco has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Caraco's claims pursuant to 35 U.S.C. § 271 (e)(5).

26. Upon information and belief, this Court has personal jurisdiction over Defendants because Defendants conduct substantial business in, and have regular and systematic contact with, this District.

27. Upon information and belief, Defendants maintain such a continuous and systematic contact with the State of Michigan and this District by conducting substantial, regular and systematic business therein through the marketing and sales of their pharmaceutical products, including LEXAPRO® – the purported commercial embodiment of the '941 patent – to allow this Court to reasonably exercise personal jurisdiction over Defendants.

28. This Court also has personal jurisdiction over Defendants because Defendants have submitted to the jurisdiction of this Court in a prior related litigation, *Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd,, and H. Lundbeck A/S. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM), which is currently pending in this Court.

29. Upon information and belief, Defendants purposefully avail themselves of the privilege of doing business in the State of Michigan and in this District.

30. Venue is proper in this District under 28 U.S.C. § 1400(b). Venue is also proper in this District under 28 U.S.C. § 1391 because, *inter alia*, Defendants are subject to personal jurisdiction in this District and because Defendants are alien corporations.

BACKGROUND

I. Regulatory Framework

A. FDA Approval Of New Drug Applications (NDAs).

31. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments and Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to

approve the marketing of both brand-name and generic drugs.

32. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare an NDA for consideration by FDA. *See* 21 U.S.C. § 355.

33. The NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

34. Upon approval of the NDA, FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

35. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent of the NDA drug before patent expiration.

36. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can

and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

37. Such conduct by the NDA-holder/patent owner gives rise to a real and concrete belief on the generic applicant's part that it will face an infringement suit, or the threat of one, if it attempts to seek approval for or to market a generic version of the NDA drug before patent expiration.

B. Generic Competition - Abbreviated New Drug Applications (ANDA).

38. Generic drugs are versions of brand-name prescriptive drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

39. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 27l(e)).

40. Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition and to expedite the marketing of lower-priced generic drug products. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

41. To receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

42. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

43. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12).

44. The submission of a paragraph 1V certification has two important consequences.

45. First, a generic applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic market exclusivity during which no other competing generic drug products may be marketed. 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit to the first filer is commonly known as "180-day exclusivity."

46. In particular, the statutory provision of the FFDCA applicable here provides that "[i]f the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this section [containing] such a

certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of: (a) the first commercial marketing of that ANDA applicant's proposed drug; or, (b) a court decision – whether it involves the first applicant or not – that the particular patent that is the subject of the paragraph IV certification is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, unless a subsequent generic applicant can obtain a court decision of noninfringement and/or invalidity as Congress intended, the approval of its ANDA can be delayed indefinitely by the purported exclusivity of the first filer.

47. Second, the submission of a paragraph IV certification for a listed patent constitutes an artificial act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

48. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued on the listed patent within the applicable 45-day period.

49. An applicant submitting an ANDA containing a paragraph IV certification must notify both the NDA holder and patent owner of its

paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

50. Upon receiving notice of the paragraph IV certification, the NDA holder/patent owner has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(c)(2)(A).

51. The NDA holder/patent owner's filing of a lawsuit prior to the expiration of 45 days prevents FDA from issuing final approval of the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

C. ANDA-Filer May Bring A Declaratory Judgment Action

52. On December 8, 2003, the MMA was signed into law. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, the Hatch-Waxman Amendments.

53. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

54. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

55. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

56. The new declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes this proceeding.

57. Congress's intent in amending 21 U.S.C. § 355 and 35 U.S.C. § 271(e) was to extend to ANDA applicants, like Caraco here, the right to file and maintain a declaratory judgment action for patent noninfringement and/or invalidity against an NDA holder/patent owner, and to direct the district court to exercise subject matter jurisdiction in such an action.

58. The purpose of this provision was two-fold, First, Congress enacted the declaratory judgment provision to allow generic applicants to obtain court decisions that would expedite the introduction of

generic drugs by allowing the generic applicant to obtain approval of its ANDA and clear up any bottleneck in the market created by another applicant's 180-day exclusivity.

59. The FFDCA provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the listed patent invalid, unenforceable or not infringed, whichever is first.

60. These events – first commercial marketing and a court decision – are, often called triggering events, because under the statute they can trigger the beginning of he 180-day exclusivity period.

61. The 180-day exclusivity can begin to run, with a court decision by any applicant, even before the first applicant has received approval for its ANDA or before the first applicant has begun commercial marketing of the ANDA product. In that case, some, or all, of the 180-day exclusivity period could expire without the first ANDA applicant marketing its generic drug.

62. Conversely, if there is no court decision on a listed patent and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period.

63. Until an eligible ANDA applicant's 180-day exclusivity period has been triggered (and expires), FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the applicants are willing to immediately begin marketing.

64. By specifically allowing declaratory actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely by the first filer's 180-day exclusivity period. A declaratory action by a subsequent ANDA filer can result in a court decision that would trigger the first filer's 180-day exclusivity period, thereby clearing the way for approval of the subsequent ANDA filer.

65. Second, Congress intended to allow generic applicants to obtain patent certainty before marketing their generic products in order to avoid potentially catastrophic infringement damages.

66. Accordingly, if the NDA holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA holder/patent owner to obtain patent certainty. Indeed, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

67. Similarly, if the NDA holder/patent owner files a lawsuit, but fails to assert a patent that was the subject to a Orange Book listing and paragraph 1V certification, the ANDA-filer is entitled to file and maintain a declaratory action against the NDA

holder/patent owner to obtain patent certainty on the non-asserted patent.

II. Caraco's ANDA No. 78-219

A. Caraco Has The Right To Bring Declaratory Lawsuit On The '941 Patent

68. In March 2006, Caraco filed an ANDA (No. 78-219) with FDA seeking generic approval for 5, 10, and 20 mg tablets of escitalopram oxalate (the "ANDA Products").

69. Defendants listed the '712 patent and the '941 patent in the Orange Book in connection with NDA No. 21323 and the brand name drug LEXAPRO®, which comprises the active ingredient escitalopram oxalate.

70. By listing the '712 and '941 patents in the Orange Rook, Defendants maintain, and have affirmatively represented to the world, that the '712 and '941 patents claim LEXAPRO®, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Caraco, that attempts to seek approval for, and market, a generic version of LEXAPRO® before the expiration of the '712 and '941 patents. The listing of the '712 and '941 patents in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer who makes a paragraph IV certification as to the '712 and '941 patents.

71. Because Caraco seeks FDA approval to market its ANDA Products before expiration of the '712 and '941 patents, Caraco's ANDA includes paragraph IV certifications to both the '712 and '941 patents.

72. On May 24, 2006, Caraco sent to Defendants a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the '712 and '941 patents are invalid, unenforceable, and/or not infringed by Caraco's ANDA Products.

73. Upon information and belief, Defendants received Caraco's notice letter of its paragraph IV certifications on May 24, 2006.

74. On July 10, 2006, Defendants filed a patent infringement lawsuit against Caraco, alleging that Caraco's ANDA Products would infringe the '712 patent. That lawsuit is currently pending in this Court.

75. Although a case or controversy exists between the parties on the '941 patent, Defendants did not bring a lawsuit that Caraco's ANDA Products would infringe the '941 patent.

76. Caraco, on its notice letter and as required under 21 U.S.C. § 355(i)(5)(C), extended to Defendants an Offer of' Confidential Access to Application to access certain information in Caraco's ANDA for escitalopram product.

77. By providing this Offer of Confidential Access to Application, and because Defendants did

not sue Caraco on the '941 patent within 45 days of receipt of Caraco's notice of paragraph IV certification, Caraco is statutorily entitled to file and maintain a declaratory judgment action against Defendants under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

B. Caraco's Need To Obtain Court Judgment On The '941 Patent

78. Caraco is not only entitled to bring this lawsuit but requires the decision of this lawsuit to avoid indefinite delays in its approval of ANDA No 78-219.

79. Upon information and belief, Caraco is not the first ANDA filer on either the '712 patent or the '941 patent.

80. Upon information and belief, Ivax Corporation is the first ANDA filer with respect to each of the '712 and '941 patents, and, thus, arguably is entitled to a separate 180-day period of exclusivity on each of the '712 and '941 patents.

81. If this is proven true, generic competition for escitalopram products may be delayed until 180 days after expiration of the '941 patent in 2023, unless Ivax begins commercial marketing of its generic escitalopram product prior to the '941 patent's expiration date. Defendants refusal to litigate the validity and/or noninfringement of the '941 patent is purposefully preventing a court decision of invalidity, unenforceability and/or noninfringement on the '941 patent, which would trigger Ivax's 180-day exclusivity period for the '941 patent, thereby

allowing generic competition to the benefit of both Caraco and the American public.

82. Moreover, until and unless Caraco obtains a court decision of noninfringement and/or invalidity on the '941 patent, it faces potentially enormous infringement liability if it commences marketing before the '941 patent expires. Caraco can alleviate this harm and obtain patent certainty only through a declaratory judgment from this Court on the '941 patent.

COUNT I

Declaration of Noninfringement of the '941 Patent

83. Caraco realleges and incorporates by reference the allegations of Paragraphs 1-82.

84. This Declaratory Action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C), and seeks a declaration that one or more claims of the '941 patent will not be infringed by the manufacture, use, or sale of Caraco's ANDA Products.

85. A present, genuine, and justiciable controversy exists between Defendants and Caraco regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Caraco's ANDA Products would infringe one or more claims of the '941 patent.

86. The manufacture, use, or sale of Caraco's ANDA Products would not infringe the claims of the '941 patent.

87. Caraco is entitled to a declaration that the manufacture, use, or sale of its ANDA Products would not infringe the claims of the '941 patent.

Prayer for Relief

WHEREFORE, Defendant Caraco Pharmaceutical Laboratories, Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Defendants as follows:

(a) declaring that Caraco has not infringed and that Caraco's manufacture, use, or sale of products covered by ANDA No. 78-219 would not infringe the claims of U.S. Patent No. 6,916,941;

(b) declaring that this is an exceptional case under 35 U.S.C. §§ 285 and awarding Caraco its attorneys' fees, costs, and expenses in this action; and

(c) awarding Caraco any further and additional relief as the Court deems just and proper.

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff,

Civil Action No. 07-CV-10737-DT

vs.

FOREST LABORATORIES, INC., et al.,
Defendants,

_____/

COVENANT NOT TO SUE CARACO PHARMACEUTICAL LABORATORIES UNDER U.S. PATENT NO. 6,916,941

WHEREAS, on or about March 23, 2006, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed Abbreviated New Drug Application ("ANDA") No. 78-219 seeking FDA approval to engage in the commercial manufacture, use and sale of generic versions of the branded drug LEXAPRO® (escitalopram oxalate)("the generic products");

WHEREAS, on or about May 24, 2006, Caraco sent a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 35(j)(2)(B)(ii) and 21 C.F.R. § 314.95" to Forest Laboratories, Inc. ("Forest") and H. Lundbeck A/S ("Lundbeck") alleging non-infringement, invalidity and/or unenforceability of U.S. Patent RE 34,712

("the '712 patent") and U.S. Patent No. 6,916,941 ("the '941 patent");

WHEREAS, on July 10, 2006, Forest and Lundbeck brought suit in the United States District Court for the Eastern District of Michigan (Case No. 2:06-cv-13143) for infringement of the '712 Patent Infringement Action"), which suit is currently pending, and wherein no claims were made based on the '941 patent;

WHEREAS, on February 20, 2007, Caraco brought suit against Forest and Lundbeck in the United States District Court for the Eastern District of Michigan, Southern Division (Case No. 4:07-cv-10737), for a declaration of non-infringement of the '941 patent ("the '941 Patent Declaratory Judgment Action"), which suit is currently pending;

WHEREAS, Forest and Lundbeck have moved to dismiss the '941 Patent Declaratory Judgment Action for lack of case or controversy;

NOW, THEREFORE, to confirm the absence of any case or controversy in the '941 Patent Declaratory Judgment Action between Forest and Lundbeck, as defendants, and Caraco, as plaintiff, regarding any infringement of the '941 patent by the generic products described by ANDA 78-219;

Forest (including Forest Holdings Ltd.) hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use, sale,

offer for sale or importation of the generic products described by ANDA 78-219; and

Lundbeck hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use, sale, offer for sale or importation of the generic described by ANDA 78-219.

THIS COVENANT shall have no impact on Forest's and/or Lundbeck's ability to assert claims against Caraco under any patents other than the '941 patent, including, without limitation, the '712 patent, nor shall it have any impact on the pending '712 Patent Infringement Action.

FOREST LABORATORIES, INC.

_____

Charles S. Ryan
Vice President, Chief Intellectual Property Counsel
Date:

H. LUNDBECK A/S

/s/John Meidahl Peterson
John Meidahl Petersen
Divisional Director of Corporate Patents and Trademarks
Date: 13 April 2007

FOREST LABORATORIES, INC.

/s/Charles S. Ryan
Charles S. Ryan
Vice President, Chief Intellectual Property Counsel
Date: April 13, 2007

H. LUNDBECK A/S

_____
John Meidahl Petersen
Divisional Director of Corporate Patents and Trademarks
Date:

PERTINENT STATUTORY AND REGULATORY PROVISIONS

The Hatch-Waxman Act provides in pertinent part:

> Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section . . . . The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug . . . . Upon approval of the application, the Secretary shall publish [such] information . . . .

21 U.S.C. § 355(b)(1).

> An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . —
>
> (I) that such patent information has not

been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii).

If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2000).

> It shall be an act of infringement to submit . . . an application under [21 U.S.C. § 355(j)] of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2).

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection . . . (j)(2)(A)(vii)(IV) of [21 U.S.C. 355], and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by

> such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5).

Food and Drug Administration regulations issued to implement the Hatch-Waxman Act provide in pertinent part:

> (c) *Reporting requirements*— . . . .
>
> (2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original Declaration.* For each patent that claims a drug substance (active ingredient), drug product (formulation and composition), or method of use, the applicant shall submit FDA Form 3542a. The following information and verification is required:
> . . . .
>
> (Q) A signed verification which states: "The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation.

I verify under penalty of perjury that the foregoing is true and correct." . . . .

21 C.F.R. § 314.53(c)(2)(i)(Q) (italics in original).

Supreme Court, U.S.
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No. 08-624

In the Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S, PETITIONERS

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD., RESPONDENT

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

The Hatch-Waxman Act provides that any generic drug manufacturer that has filed an abbreviated new drug application with the FDA, and wishes to establish that its product does not infringe any Orange Book-listed patent of the name-brand drug, may bring a declaratory judgment action for that purpose. The Act vests the federal courts with subject matter jurisdiction over such actions "to the extent consistent with the Constitution." 31 U.S.C. § 271(e)(5).

Within that framework, the question presented is:

Whether a name-brand drug manufacturer's unilateral "covenant not to sue" for infringement of an Orange Book-listed patent deprives the federal courts of Article III jurisdiction to hear a generic drug manufacturer's challenge to that patent, where (1) the covenant not to sue does not concede that the generic product does not infringe the patent, and (2) the generic drug manufacturer is barred from entering the market and selling its product absent a judicial ruling on non-infringement.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, respondent Caraco Pharmaceutical Laboratories, Ltd. states that it is a subsidiary of Sun Pharmaceutical Industries Ltd., which is the only publicly held company owning 10% or more of Caraco's stock.

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BRIEF FOR RESPONDENT IN OPPOSITION

This case involves the question whether federal courts possess jurisdiction under the Hatch-Waxman Act to resolve a generic drug manufacturer's challenge to Orange Book-listed patents, where the patentee agrees not to sue for infringement but refuses to concede that the generic product does not infringe. Applying settled principles of Article III jurisprudence, the court of appeals issued a carefully reasoned opinion concluding that respondent Caraco suffered an injury in fact (exclusion from the market for generic Lexapro®) that is traceable to petitioners' conduct (listing their patents in the Orange Book) and redressable by a finding of non-infringement—which would accelerate Caraco's market entry, potentially by several years.

The result below is compelled by this Court's recent decision in *MedImmune, Inc.* v. *Genetech, Inc.*, 549 U.S. 118, 128 (2007), which held that a paid-up patent licensee was injured by having to pay royalties on a patent—and thus could challenge its validity in federal court—even though the licensee was subject to "no risk" of infringement liability. As the court of appeals recognized, Caraco's injury is much greater: it is not merely forced to pay royalties on the sales of its product; it is forbidden from selling that product *at all*, for as long as there is an unresolved dispute over the underlying patents. But even if the court below had misapplied *MedImmune* (and it did not), certiorari would not be warranted to address the application of a recent precedent of this Court to a particular case arising on an interlocutory basis in the unique context of the pre-2003 Hatch-Waxman Act. Indeed, not *one* Federal Circuit judge voted to grant rehearing.

Aware that the court below broke no new ground in terms of standing law, petitioners attempt to portray its decision as having created a new cause of action—one unauthorized by the statute. As explained below, however, the decision below faithfully implements the Hatch-Waxman Act—which entitles *any* generic manufacturer that files an abbreviated new drug application to a judicial decision on whether its product infringes the patents at issue, and which provides that a ruling in favor of *any* such generic manufacturer can trigger the first filer's 180-day exclusivity period. Review should therefore be denied.

STATEMENT

A. The Hatch-Waxman statutory scheme

This case arises under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Act"), 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271, which governs the approval of new and generic drugs. The Act is designed to "[strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." Pet. App. 3a.

1. Abbreviated new drug applications

To streamline the approval of generic drugs, the Act allows drug manufacturers to submit to the Food and Drug Administration ("FDA") an abbreviated new drug application ("ANDA"), instead of a full new drug application ("NDA"). 21 U.S.C. § 355(j)(2)(A). The ANDA process allows generic manufacturers to rely on safety and efficacy studies previously submitted by name-brand companies in NDAs. The timing and approval of an ANDA, however, depends largely

on the patent protections covering the name-brand drug. Pet. App. 4a; *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

When a name-brand drug company files an NDA, it must identify all non-process patents that protect the new drug. 21 U.S.C. § 355(b)(1), (c)(2). Exercising a "ministerial duty" (Pet. 6), the FDA lists these patents in its book of "Approved Products With Therapeutic Equivalence Evaluations"—the "Orange Book." In filing its ANDA, a generic manufacturer must include one of four certifications for each patent listed in the Orange Book: (I) a statement that the required information relating to the patent has not been filed with the FDA; (II) a statement that the patent has expired; (III) a statement that the patent will expire on a particular date; or (IV) a statement that the patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These certifications are known as Paragraph I, II, III, and IV certifications, respectively.

When, as in this case, an ANDA contains a Paragraph IV certification challenging an Orange Book-listed patent, the Act treats the filing of the ANDA as an act of patent infringement (35 U.S.C. § 271(e)(2)), and the patentee may sue the ANDA applicant for infringement. If the patentee does not sue within 45 days, the FDA may approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues, however, the ANDA is automatically stayed for 30 months or until a court holds each listed patent not infringed (or invalid), whichever comes first. *Ibid.* "[T]he purpose of subsection[] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme rests." *Eli Lilly*, 496 U.S. at 678.

To "incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible," the pre-2003 version of the Act, at issue here, provides 180 days of market exclusivity for the generic applicant that is the first to challenge each Orange Book-listed patent. Pet. App. 6a. This "first applicant" or "first filer" receives a 180-day monopoly on the right to market its generic drug, which is triggered on either the date that it begins such marketing (the "commercial-marketing trigger") or the date of any final court decision finding the challenged patent invalid or not infringed (the "court-judgment trigger")—whichever comes first. Pet. App. 6a-7a; see generally *Teva Pharm. USA, Inc.*, v. *Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005).

Subsequent ANDA filers may not receive FDA approval until the first applicant's 180-day exclusivity period has expired. 21 U.S.C. § 355(j)(5)(B)(iv). This creates a potential "bottleneck": if the first applicant cannot (or does not) use its exclusivity, the patentee can leverage the unexpired exclusivity to keep other generics out of the market, sometimes for decades. For example, if the first applicant unsuccessfully challenges one of the listed patents for which it was the first Paragraph IV filer, other generic applicants remain barred from entering the market—unless they can obtain a court decision holding the other patents not infringed or invalid. *Ibid.* Patentees thus have a tremendous incentive "to insulate [their] patent[s] from any validity challenge" and "from any judicial determination of the[ir] metes and bounds." *Teva Pharm. USA, Inc.* v. *Pfizer Inc.*, 405 F.3d 990, 993 (Fed. Cir. 2005) (Dyk, J., dissenting from denial of rehearing en banc).

Patentees attempt to insulate their drug patents from challenge in several ways: (1) by opportunistically suing on only one Orange Book-listed patent while holding the others in reserve for future litigation, *e.g.*, *Teva Pharm. U.S.A., Inc.* v. *Novartis Pharm.*, 482 F.3d 1330, 1343 (Fed. Cir. 2007); (2) by settling on advantageous, duopolistic terms with the first ANDA applicant and refusing to litigate with later applicants, *e.g.*, *Teva*, 405 F.3d at 993 (Dyk, J., dissenting from rehearing en banc); and—as here—(3) by suing subsequent ANDA applicants on one listed patent while covenanting not to sue on the others. Each of these actions injures subsequent ANDA applicants, frustrates "early resolution of patent disputes," *Novartis*, 482 F.3d at 1344, and undermines "Congress's intent to foster early generic market entry," *Teva*, 405 F.3d at 995 (Dyk, J., dissenting from denial of rehearing en banc).

2. The "civil action to obtain patent certainty"

"[T]o prevent patentees from 'gaming' the Hatch-Waxman Act," Congress enacted the "civil action to obtain patent certainty" (or "CAPC"). *Novartis*, 482 F.3d at 1342. The CAPC allows any ANDA applicant to bring a declaratory judgment suit challenging any Orange Book-listed patent. 21 U.S.C. § 355(j)(5)(C). As Congress recognized:

> [When] the brand drug company [attempts] . . . to delay a final court decision that could trigger [the first filer's exclusivity] . . . generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book . . . because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (Sen. Kennedy).

Such a "declaratory action is the ideal method to police [patentees'] strategic manipulation of the Hatch-Waxman exclusivity provisions" (*Teva*, 405 F.3d at 995 (Dyk, J., dissenting from denial of rehearing en banc)) and to "facilitate[] the early resolution of patent disputes between generic and pioneering drug companies." Pet. App. 5a. The Act thus extends federal jurisdiction over these ANDA declaratory judgment actions to the full extent permitted by the Constitution. 35 U.S.C. § 271(e)(5).

B. Caraco's ANDA

Forest holds an FDA-approved NDA for Lexapro®, which comprises the active ingredient escitalopram oxalate. Lexapro®, a profitable anti-depressant, generates more than $2 billion in annual sales—over half of Forest's gross revenue. Forest currently faces no generic competition on Lexapro®. *Forest Labs., Inc.* v. *Ivax Pharm., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

Forest's NDA for Lexapro® listed two patents in the Orange Book: U.S. Patent Nos. Re. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). The '712 patent, which expires in 2012, is directed to "substantially pure" forms of escitalopram; the '941 patent, which expires in 2023, is directed to particles of escitalopram oxalate with an average size of forty microns. *Ibid.*[1]

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[1] After the decision below, Forest listed a third patent—U.S. Patent No. Re. 7,420,069. Pet. 12 n.6. On November 26, 2008, Caraco filed a Paragraph IV certification challenging this patent, which like the '941 patent expires in 2023. This patent does not change the jurisdictional analysis. For simplicity, therefore, we refer only to the '712 and '941 patents.

Caraco wishes to market a generic version of Lexapro® based on particles of less than three microns. Caraco's ANDA, filed in 2006, challenged both of Forest's Orange Book-listed patents.

C. Ivax's exclusivity

Ivax Pharmaceuticals, not Caraco, was the first generic to file Paragraph IV certifications challenging Forest's '712 and '941 patents. To block approval of Ivax's ANDA, Forest sued Ivax on the '712 patent (but not the '941 patent). The Federal Circuit held that the '712 patent was valid, and that Ivax's proposed generic drug infringed it. *Forest*, 501 F.3d at 1272. At that point, Ivax lost its exclusivity on the '712 patent.

Having failed to obtain a favorable ruling on the '712 patent, Ivax is barred from entering the market for generic Lexapro® until the '712 patent expires in 2012 or another applicant defeats that patent. And because Ivax has a right to 180 days of market exclusivity on the '941 patent (as first filer on that patent under the pre-2003 provisions at issue here), no other generic manufacturer can enter the market until 180 days after Ivax—*i.e.*, until at least 180 days after the '712 patent expires in 2012—even if that manufacturer has a non-infringing product.

The Act allows subsequent generic ANDA filers to clear this "bottleneck" in one of two ways. In the immediate term—*i.e.*, before the '712 patent expires in 2012—they must successfully challenge both listed patents. In the slightly longer term—*i.e.*, after the '712 patent expires in 2012—they need only successfully challenge the second patent. After (1) both patents are ruled invalid or not infringed, or (2) the first patent has expired and the second has been ruled in-

valid or not infringed—either of which would trigger Ivax's 180-day exclusivity period—Caraco (and possibly other generics) can enter the market for generic Lexapro®.

Forest therefore has a strong incentive "to do everything possible to prevent its patents from being put in play." *Teva*, 405 F.3d at 994 (Dyk, J., dissenting from denial of rehearing en banc). As long as Forest can prevent the courts from ruling on its patents, it can bar all generic competition on Lexapro®, possibly until 2023, but certainly until 2012.

D. The district court's decision

As with Ivax, Forest sued Caraco on the '712 patent—but not the '941—to block approval of Caraco's ANDA while insulating the '941 patent from challenge. Desiring to clear the "bottleneck," Caraco filed a CAPC against Forest, seeking "a declaration that one or more claims of the '941 patent will not be infringed by [Caraco's product]." Pet. App. 99a.

Forest moved to dismiss the suit, initially arguing that there was no jurisdiction because Caraco lacked a "reasonable apprehension" that it would be sued for infringement. Following *MedImmune*, however, the Federal Circuit abandoned the "reasonable apprehension of suit" test in *Novartis*, 482 F.3d at 1338-1339. As the court there recognized, the fact that Caraco "is not legally free to enter the market . . . [is] a direct legal injury [caused by] the actions that [Forest] ha[d] already taken—[Forest's] listing of [its] patents in the Orange Book and [Forest's] suit against [Caraco] challenging the validity of [Caraco's] ANDA." *Id.* at 1345. The dispute over the '941 patent thus involves "a present injury sufficient for a justiciable controversy." *Ibid.*

Fifteen days after *Novartis*, and in a desperate attempt to avoid a ruling on Caraco's claim, Forest granted Caraco a unilateral "covenant not to sue" on the '941 patent and asserted that this "mooted" the controversy. Pet. App. 19a. Yet Forest refused to concede that the '941 patent was not infringed. Instead, Forest argued that the court should dismiss the case because eliminating the threat of infringement liability relieved Caraco of its only injury. *Id.* at 21a.

After twice changing its mind during argument, the district court dismissed the case without written opinion. The court did not explain why the continuing controversy over infringement of the '941 patent (which Forest refused to concede) or the delayed entry to market due to that controversy was insufficient to support standing. It simply applied the discredited "reasonable apprehension of suit" test, stating: "There's a covenant not to sue on the '941 so there's . . . no threat of a lawsuit . . . and no controversy." Pet. App. 77a-78a. The court of appeals found "no indication in the record that the district court considered either the Supreme Court's *MedImmune* decision or [the Federal Circuit's] *Novartis* decision when making this ruling." *Id.* at 20a.

E. The court of appeals' decision

The Federal Circuit reversed. Observing that the "reasonable-apprehension-of-suit test was overruled by *MedImmune*," the court explained that jurisdiction no longer turned solely on the risk of an infringement suit. Pet. App. 22a. Rather, the court was "guided by the Supreme Court's three part framework for determining whether an action presents a justiciable Article III controversy," under which "proving a reason-

able apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test." *Id.* at 22a, 23a.

The court went on to explain that "Caraco's alleged injury-in-fact"—"being excluded from selling a non-infringing product"—is "precisely the type of injury that the Declaratory Judgment Act is designed to remedy." Pet. App. 24a, 29a. "[A] potential competitor in other fields is legally free to market its product in the face of an adversely held patent," the court explained, whereas "an ANDA filer . . . is not legally free to enter the market [without FDA approval]." *Id.* at 24a. But "[i]f Caraco is correct that its generic drug does not infringe Forest's [patents], then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions . . . is exactly the type of injury-in-fact that is sufficient to establish Article III standing." *Id.* at 25a.

Turning to the traceability prong of standing, the court held that "[i]t is not the Hatch-Waxman Act or the FDA framework that prevents Caraco's ANDA from being approved by the FDA, but rather Forest's actions." Pet. App. 26a. Specifically, in "list[ing] its [Lexapro®] patents in the FDA's Orange Book," Forest "create[d] an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete"—"even if [Caraco's product] does not infringe" the Lexapro® patents. *Id.* at 26a-27a. Citing several precedents of this Court, the court found it "well settled that the creation of such barriers to compete satisfies the causation requirement of Article III standing." *Id.* at 27a.

As to redressability, the court reasoned that "a declaratory judgment . . . would clear the path to FDA approval that Forest's actions would otherwise deny Caraco"—and thus "eliminate the potential for the '941 patent to exclude Caraco from the drug market." Pet. App. 27a-28a. "In claiming that it has been denied the right to sell non-infringing drugs," Caraco alleged "the exact type of uncertainty of legal rights that the ANDA declaratory judgment action . . . was enacted to prevent." *Id.* at 25a, 29a.

The court further held that the case was ripe. Delaying Caraco's suit would "ha[ve] the 'immediate and substantial impact' of forestalling Caraco's ability to activate Ivax's exclusivity period through the court-judgment trigger"—delaying Caraco's market entry "until at least 181 days after the '712 patent expires in 2012," if not "indefinitely," and generating "lost profits." Pet. App. 26a, 32a-34a.

As to mootness, the court acknowledged that "[i]f a threat of suit was the *only* action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case." Pet. App. 34a (emphasis added). But "[a] controversy *also* exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA," and "the controversy can only be resolved by a judgment that determines whether Forest's '941 patent is infringed." *Id.* at 37a (emphasis added). Thus, "Forest's covenant not to sue does not eliminate the controversy." *Ibid.*

Judge Friedman dissented. In his view, the possibility that a first ANDA filer "might not market its product upon either the expiration of the thirty month stay period or of the patents" is too "uncertain"

to support a declaratory judgment action. Pet. App. 39a. He did not dispute, however, that being kept out of the market injures Caraco, that Caraco's injury is traceable to Forest, or that *even if* Ivax went to market in 2012, a judgment invalidating the '712 and '941 patents *prior to* that date would enable Caraco to enter the market earlier (potentially by years) than it otherwise could. Nor did the dissent take issue with the legal standards applied by the majority. *Id.* at 40a. He simply believed that Caraco's only injury depended on whether Ivax delayed entering the market in 2012, and that this injury was not ripe.[2]

REASONS FOR DENYING THE PETITION

Petitioners concede that "the CAPC action should be interpreted as broadly as possible consistent with the bounds of Article III." Pet. 22. Not surprisingly, they do not suggest that Caraco's exclusion from the market is an insufficient injury to support standing. Nor do they dispute that Forest's listing of its patents in the Orange Book is one significant "but for" cause of Caraco's delayed market entry, or that a ruling in Caraco's favor would redress that injury. In short, there is no dispute over the basic principles of Article III jurisdiction that govern this dispute—or even, for the most part, over how they apply.

Rather, the petition rests on two statutory arguments. First, noting that "an injury must be action-

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[2] Judge Friedman also believed that, even under the pre-2003 Act, a first ANDA filer can "lose its right to exclusivity" if it "unreasonably delays" marketing its product. But as the court of appeals recognized (Pet. App. 32a), since Ivax filed its ANDA before Congress passed the "failure to market provision" (21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)), that provision does not govern Ivax's exclusivity.

able" to support standing, petitioners say the court below "recast the familiar cause of action for patent infringement as a cause of action that Congress has never seen fit to create." Pet. 15, 17. Second, they say that Caraco's injury is not attributable to Forest because Forest was "compelled" to list its patents in the Orange Book, and because any 180-day delay is caused by Ivax's "first filer" status. Both of these arguments, however, mischaracterize the Hatch-Waxman Act and the extent of Caraco's injury.

As explained below, the Act grants not only the first ANDA filer, but *any* ANDA filer, the right to a decision on whether its product infringes any listed patents; moreover, a ruling in favor of *any* such ANDA filer can trigger the first filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Thus, there is no basis to petitioners' suggestion that the court below recognized a cause of action not authorized by Congress.

Moreover, listing its patents in the Orange Book was "mandatory" only insofar as Forest wished to receive the benefit of a monopoly protected by the Act's stringent patent enforcement system—a benefit that depends on the validity and lawful scope of those patents. And quite apart from any delay attributable to Ivax's 180-day exclusivity period, Forest's listing of its patents *independently* causes Caraco to experience market delay—potentially several years' worth of delay—that more than suffices to support standing.

Beneath petitioners' mischaracterizations of the Act, all that remains is their quarrel with the court of appeals' carefully-reasoned application of settled jurisdictional principles to a particular Hatch-Waxman dispute. But the decision below is compelled by this

Court's decision just two Terms ago in *MedImmune*, which held that declaratory relief remains available even *absent* risk of infringement liability, provided there remains a substantial controversy between the parties—which exists here on account of Forest's refusal to concede non-infringement. And even if the court below had misapplied *MedImmune*, there would be no need for the Court to take up the general principles that govern standing in patent cases for the second time in as many years—particularly in this case, which is a relic of the pre-2003 statutory regime. Certiorari should therefore be denied.

I. The Petition Provides No Basis For Reviewing The "Legally Protected Interest" Holding Of The Decision Below.

Forest acknowledges (as it must) Congress's power to define what constitutes a "legally protected interest." Pet. 17. As this Court has observed, "Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy." *Massachusetts* v. *EPA*, 549 U.S. 497, 516 (2007). Moreover, Forest does not dispute that being kept out of the market is a cognizable Article III injury. Nor could it. Numerous decisions of this Court, recognized by the court of appeals (Pet. App. 27a), confirm that "a barrier that makes it more difficult" to "compete on an equal footing" can support standing. *E.g.*, *Northeastern Fla. Chapter, Assoc. Gen. Contractors of Am.* v. *Jacksonville*, 508 U.S. 656, 666 (1993).

Unable to quarrel with the general principles that govern whether Caraco has suffered an injury, Forest attempts to justify review by maintaining that Hatch-Waxman offers no protection for Caraco's interest in

entering the market with a non-infringing product. According to Forest, the Federal Circuit "recast the familiar cause of action for patent infringement" as one "premised on a nonexistent right to seek review of any action by a pioneer drug company that contributed to preventing a generic company from marketing its drug." Pet. 15, 20.

Even if this were so, it would raise only a question of statutory interpretation, not standing, and Forest has not sought review of the Federal Circuit's reading of the Act. See Pet. i (raising only jurisdictional issues). Any complaint that the court below misread the Act is not presented by the petition and cannot support certiorari. As shown below, however, the petition badly mischaracterizes both the Act and the reach of the decision below. Certiorari is therefore unwarranted for that reason as well.

A. Forest's assertion that the decision below rewrote the "civil action to obtain patent certainty" mischaracterizes the Hatch-Waxman Act.

To read the petition, one would think the Hatch-Waxman Act granted only *first* ANDA filers the right to challenge name-brand drug companies' patents. Yet Forest fails to provide any reason to question the Federal Circuit's conclusion that *any* generic's inability to market its product due to a name-brand company's patent listings is an injury that the CAPC is designed to address.

Indeed, with one exception discussed below (the Federal Circuit's recent *Janssen* decision, which Forest misinterprets), Forest cites not a single authority to support its assertion that subsequent ANDA applicants have no cognizable interest in obtaining rulings

that their products do not infringe—and thus in getting their ANDAs approved. See Pet. 20-25. Instead, Forest simply *assumes* that avoiding liability for infringement is Caraco's only "legally protected interest," and proceeds from that assumption to lambaste the jurisdictional analysis of the court below. But Forest's assumption is wrong—and once that becomes clear, nothing remains of its suggestion that the court below departed from "bedrock" principles of Article III standing.

When a generic drug maker's ANDA contains a Paragraph IV certification challenging the infringement (or validity) of an Orange Book-listed patent, the Act treats the very filing of the ANDA as an act of patent infringement. 35 U.S.C. § 271(e)(2). NDA filers such as Forest are well served by this provision—which this Court has recognized as necessary "to enable the judicial adjudication upon which the ANDA . . . scheme rests." *Eli Lilly*, 496 U.S. at 678.

But to "level the playing field" (*Novartis*, 482 F.3d at 1342), the CAPC also permits *any* ANDA filer—whether the first or any other—to obtain a decision on whether each patent at issue is invalid or not infringed. Similarly, any ANDA filer can set in motion the 180-day exclusivity period, and speed its FDA approval, by obtaining a favorable decision on the merits. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); 21 U.S.C. § 355(j)(5)(C); see also *id.* § 355(j)(5)(D)(i)(I)(bb)(AA) (providing that a successful CAPC by "any other applicant" can trigger forfeiture of the first filer's exclusivity). The Act thus grants *each* ANDA applicant a statutory right to a ruling on whether its generic product infringes valid Orange Book-listed patents.

What is more, Congress extended jurisdiction over such declaratory judgment actions to the full extent permitted by the Constitution. 31 U.S.C. § 271(e)(5). Without analysis or citation of authority, Forest declares that "the Federal Circuit erred in converting that interpretive instruction into an authorization to create a freestanding cause of action for any injury experienced by ANDA filers traceable in any respect to the blocking patent holder." Pet. 22. But the Federal Circuit has done no such thing. It has merely held—in decisions of three different panels—that the CAPC reaches disputes over infringement that block an ANDA filer's ability to reach market with a non-infringing product. See Pet. App. 25a, 29a; *Novartis*, 482 F.3d at 1345; *Janssen Pharmaceutica, N.V.* v. *Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008).

Indeed, even if the question "is whether the civil action to obtain patent certainty . . . creates a private right of action apart from redressing disputes over infringement" (Pet. 19), there *is* a dispute over infringement here. Forest carefully crafted its unilateral "covenant not to sue" to avoid conceding non-infringement. True, Caraco faces no risk of *liability* for infringement. But as the court below recognized (Pet. App. 25a), potential liability is not the only type of harm that declaratory judgment suits are designed to prevent (let alone the only type of harm that Article III recognizes). Suits seeking a declaration that one's product does not infringe a competitor's patents also prevent harm in the form of delayed market entry, and such an injury undisputedly satisfies Article III. Indeed, all that Forest has done is promise not to sue Caraco for damages that Caraco cannot inflict: If Caraco may not pursue its claim, then it cannot bring its product to market regardless of the covenant; and

if Caraco prevails, its product is non-infringing and Forest could not sue it regardless of the covenant.[3]

In sum, even if the court below had misread the scope of the CAPC, that mistake would be a matter of statutory interpretation on which Forest has not sought review; it would not amount to a conflict in the law of standing, let alone a "judicial legerdemain" regarding any "bedrock constitutional requirement." Pet. 15. But in any event, the court properly interpreted the scope of the CAPC. Accordingly, review should be denied.

B. Petitioners' policy-based concerns are unfounded.

Once it becomes clear that Forest's objection to the decision below is foreclosed by the Act itself, nothing remains of the parade of policy horribles offered to support certiorari.

1. For example, Forest and its amici assert that the decision below upsets the Act's "careful balance" between innovation and competition. Pet. 31-35; Ivax Br. 3-5; Pfizer Br. 19-21; WLF Br. 21-22. But since Congress provided that *any* ANDA filer could bring a declaratory judgment action to challenge the listed patents (and, if successful, trigger the 180-day exclusivity period), the ruling at issue in fact implements that balance.

Indeed, an ANDA filer's CAPC is especially appropriate where, as here, the first filer has unsuccessfully challenged one of the listed patents. Able to

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[3] The '941 patent claims escitalopram particles with an average size of forty microns—versus *three* microns for Caraco's product. Forest is playing games with the Hatch-Waxman framework because it cannot establish infringement.

avoid subsequent ANDA filers' challenges, the patentee in such cases—with a victory over the first filer on a single patent—could prevent all other generics from challenging the listed patents (and entering the market) simply by granting covenants not to sue. Such gaming of the system would gut Congress's provision for multiple challenges to the listed patents—the statutory right to obtain a decision even when the first filer's suit fails. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); 21 U.S.C. § 355(j)(5)(C). It would also be the antithesis of "enabl[ing] competitors to bring cheaper, generic . . . drugs to market as quickly as possible"—the "central purpose of the Hatch-Waxman Act." *Novartis*, 482 F.3d at 1344.[4]

After all, first filers' Paragraph IV certifications need not be correct, just complete. 21 U.S.C. § 355(j)-(5)(B)(iv)(II)(bb); Pet. App. 6a. Thus, as the D.C. Circuit observed in *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), allowing subsequent ANDA filers to use a declaratory judgment action to reach market is not only "textually persuasive," but also "a particularly appropriate solution in cases in which the second applicant has done a better job of designing around the pioneer drug manufacturer's patent than the first did: in such cases, the second applicant should find it (relatively) easy to win a declaratory judgment action against the pat-

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[4] Petitioners disclaim "gaming" the Act, noting that "avoiding the costs, uncertainty, and disruption of litigation are legitimate ends in themselves." Pet. 30. Indeed they are. But to quote petitioners, "no tears should be shed for [Forest]." *Id.* at 33. If not being "conscripted" to participate in "needless litigation" were Forest's objective (*ibid.*), it could easily be accomplished by stipulating to non-infringement and the entry of a consent decree. See Pet. App. 28a n.11.

ent-holder. [*This*] *reading thus rewards those applicants (and only those applicants) who have built a better mousetrap.*" *Id.* at 1073 (emphasis added). Caraco alleges that it has built a better mousetrap. Forest has no right to shield itself with Ivax's failure.[5]

2. Forest and its amici nonetheless complain that it is unfair for subsequent ANDA filers to be able to run off the first filer's 180-day exclusivity period before that first filer—whose own challenge to the earliest-expiring patent failed—can go to market. Pet. 33-34; Ivax Br. 3-4; Pfizer Br. 19. This argument, however, is not an argument for certiorari, but rather a policy objection to Congress's decision to permit any ANDA filer to trigger the first filer's exclusivity.

Moreover, petitioners' argument is of diminishing importance in light of the 2003 amendments to the Act. Under the pre-2003 provisions at issue here, the 180-day exclusivity period may be triggered on a *patent-by-patent* basis; but under the post-2003 law, the 180-day period applies on a *product-by-product* basis, such that *no* ANDA filer may qualify for exclusivity by challenging patents added to the Orange Book *after the first ANDA filing*. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, fewer and fewer cases will involve situations in which a first filer loses its exclusivity period on one patent, yet retains another period (based on another patent) that is put at risk in the litigation necessary for subsequent ANDA filers to reach market. For ex-

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[5] Forest asserts that *Mova* identified two distinct problems for ANDA applicants trying to reach market: the reasonable-apprehension-of-suit test *and* the case-or-controversy requirement. Pet. 4. But in fact, the problems were one and the same: the case or controversy requirement *as then applied by the Federal Circuit*. See 140 F.3d at 1073.

ample, Forest listed its '941 patent after Ivax's ANDA was filed. If the new law applied, Ivax's exclusivity would have depended entirely on its challenge to the '712 patent: Ivax would have forfeited that exclusivity period when it failed to defeat the '712 patent, and Ivax would therefore have nothing at stake in this litigation. See *id.* § 355(j)(5)(D). This case is a relic of the pre-2003 regime.

3. Petitioners say "the incentives for first filers have to be set *ex ante* behind a veil of ignorance," and they accuse the court below of allowing "other generics to take their own separate shots at piercing [Forest's] patent" based on "*ex post* knowledge that Ivax's patent litigation against Forest had failed." Pet. 32. But while the Act's incentive scheme must be analyzed apart from the outcome of particular cases, it is *Congress* that authorized all ANDA filers (not just first filers) to bring CAPCs; it is *Congress* that provided federal jurisdiction to hear such suits to the extent permitted by the Constitution; and it is *Congress* that provided for any ANDA filer's successful declaratory judgment suit to trigger the 180-day exclusivity period. Thus, insofar as the court below permitted "other generics to take their own separate shots at piercing [Forest's] patent," it was carrying out *Congress's* intent. Forest can suggest otherwise only by ignoring the Act's text.

4. Amicus Pfizer (Br. 8-10) wrongly equates the decision below with a rejected Senate bill that would have created "automatic jurisdiction" by providing that the filing of a Paragraph IV certification and the failure of the NDA holder to sue for infringement would "establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts." S. 1, 108th

Cong. § 702(c) (2003). But as the court below recognized, the *enacted* law granted jurisdiction "to the extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)), and that language expresses Congress's intent while acknowledging that "it is ultimately the province and duty of the judicial department, not Congress, to discern the limits of Article III." Pet. App. 31a n.13 (citing *Marbury* v. *Madison*, 5 U.S. (1 Cranch) 137 (1803)). The court below thus considered the specific facts here under *MedImmune*'s "all-the-circumstances test." *Id.* at 23a. Its analysis was the opposite of a formulaic, "automatic jurisdiction" approach.

C. The decision below does not conflict with this Court's decisions, and is compelled by *MedImmune*.

Forest also says the court below "ran roughshod over decisions of this Court." Pet. 15. But apart from asserting that the court contravened *Lujan* by misinterpreting the scope of the CAPC, Forest makes no attempt to demonstrate a conflict with this Court's decisions. More importantly, Forest offers no convincing argument that this Court's decision just two Terms ago in *MedImmune* does not compel the outcome below.

The plaintiff in *MedImmune* was a paid-up patent licensee who sought a declaratory judgment that the underlying patent was not infringed by the licensee's product. A fully-paid patent license is no different from a covenant not to sue—indeed, a fully-paid license *is* "an enforceable covenant not to sue." *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004). Moreover, the licensee in *MedImmune*, like Caraco here, faced "no risk" of infringement li-

ability. 549 U.S. at 128. Yet the Court found a controversy sufficient to support jurisdiction because the plaintiff had to pay royalties on a patent that it allegedly did not infringe. *Id.* at 128-130. Here, the injury is *greater*: Caraco is not merely required to pay royalties on the sale of generic Lexapro®; it is forbidden from selling generic Lexapro® *at all*, so long as there remains an unresolved dispute over infringement of the '941 patent.

Petitioners dismiss *MedImmune* by arguing that it "did not involve Hatch-Waxman" and "held only that a patent licensee could pay royalties under protest without mooting its . . . declaratory judgment action." Pet. 2, 3; accord WLF Br. 17. But in fact, the governing principles and the injury at issue—lost revenue due to a patent that the declaratory judgment plaintiff alleges is not infringed—are the same. If a paid-up license (an "enforceable covenant not to sue") did not destroy jurisdiction in *MedImmune*—where the plaintiff was free to sell its product—then Forest's covenant does not destroy jurisdiction *a fortiori*.

D. The Federal Circuit's post-*MedImmune* standing cases are not in conflict.

Lacking a serious argument that the decision below conflicts with the decisions of this Court, Forest and its amici attempt to find disarray in the Federal Circuit's standing decisions. Pet. 25; Pfizer Br. 14-19. As shown below, however, the Federal Circuit's post-*MedImmune* cases are consistent, and there is certainly no need for a second review of its standing doctrine in as many years. ROBERT L. STERN ET AL., SUPREME COURT PRACTICE § 6.37 at 459 (8th ed. 2002) ("The Court is too busy to supervise every application of its precedents to particular facts and circum-

stances, even if a given application is arguably wrong," "particularly if it has recently addressed an issue and the lower courts are just beginning to apply the rule it has declared").

1. The first note in the "cacophony" of precedent about which Forest complains is a "line of cases holding that the granting of a covenant not to sue for infringement moots a declaratory judgment action to resolve an infringement dispute." Pet. 21 n.10, 23. The cases cited, however, either have nothing to do with Hatch-Waxman, pre-date *MedImmune*, or both. Thus, they do not conflict with the decision below.

In an ordinary infringement case—where the only question is whether the plaintiff's actions expose it to liability—a covenant not to sue allows the recipient to enter the marketplace and thereby moots the case. That is why the covenants in the cases cited by Forest eliminated jurisdiction—a point the court below recognized. See Pet. App. 34a-35a.

In the Hatch-Waxman context, by contrast, a covenant not to sue does not *eliminate* the non-first filer's barrier to market entry; it *perpetuates* that injury by preventing that generic from obtaining the judgment of invalidity or non-infringement needed for FDA approval. Pet. App. 35a-36a. Thus, decisions holding that a covenant not to sue eliminates jurisdiction in a typical patent infringement case do not conflict with the ruling below.

2. Forest also relies on Federal Circuit cases holding that a plaintiff lacked an interest protected by the Patent Act. Pet. 23. Here again, however, Forest asserts rather than demonstrates that the decision below misinterpreted the scope of the CAPC. As shown above, Forest is wrong; but even if it were correct,

these cases do not remotely establish an intra-circuit conflict. Rather, they show that the circuit's *Lujan* case law is of a piece in recognizing that standing may be "founded upon a viable cause of action" (*ibid.*)—and that Forest's complaint is an (unfounded) objection to the court's reading of the CAPC.

3. Finally, Forest asserts that the Federal Circuit in *Janssen* "appeared to recognize, in conflict with the holding here, the absence of a legally cognizable injury." Pet. 24; accord Pfizer Br. 15-17. But as Forest acknowledges, *Janssen* expressly reaffirmed *Caraco*, distinguishing it on the ground that the generic manufacturer there (Apotex) "stipulated that the earliest expiring patent was valid and infringed." Pet. 24. As the court there explained:

> The key difference between *Caraco* and this case is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in *Caraco* ceased to exist once Apotex stipulated to the validity, infringement, and enforceability of the [first-to-expire] patent. Therefore, *unlike Caraco, Apotex cannot claim that . . . it was being excluded from selling a noninfringing product by an invalid patent*—it stipulated to the validity of the [first-to-expire] patent. Even if Apotex successfully invalidates the [later-expiring] patents, it cannot obtain FDA approval until the expiration of the [first-to-expire] patent because of its stipulations with respect to that patent.

540 F.3d at 1361 (emphasis added).

Janssen did not question that the delayed market entry suffered by Caraco is a cognizable injury, that it is traceable to Forest, or that it will be redressed if Caraco prevails. Nor did it hold, as Forest asserts,

"that the generic's declaratory judgment claims with respect to the latter two patents were moot." Pet. 24. It simply held that a generic's CAPC challenge to one patent is not *ripe* while another, admittedly valid and infringed patent remains in force and independently precludes market entry. Because Caraco maintains that each of Forest's Lexapro® patents is invalid or not infringed, there is no conflict between *Janssen* and the decision below. See also *Minnesota Mining & Mfg. Co.* v. *Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002) (a patentee's infringement suit against a generic ANDA applicant was justiciable even *after* the patentee conceded non-infringement, where the parties' disagreement over whether dismissal should be with prejudice directly affected the timing of the generic's market entry).

Forest admits that Caraco's challenge to Forest's earliest-expiring patent creates a "significant difference between *Janssen* and this case," yet says this is irrelevant because the name-brand company there argued on rehearing that the decision below should be overruled. Pet. 24-25. Any discomfort that the name-brand company may have felt about its victory in *Janssen*, however, likely stemmed from *Janssen*'s *consistency* with the decision below—such that Apotex may refile its suit when its injury from the later-expiring patents ripens.

In sum, petitioners fail to support their assertion that the Federal Circuit is "confused about the protectable-right requirement of *Lujan*." Pet. 25. The very cases on which they rely demonstrate the court's diligence in ensuring that plaintiffs have a protected legal interest related to the patent at issue.

II. The Petition Provides No Basis For Reviewing The Court Of Appeals' Holding That Caraco's Injury Is "Fairly Traceable" To Forest.

Aware that "exclusion from the generic drug market . . . is exactly the type of injury-in-fact that is sufficient to establish Article III standing" (Pet. App. 25a), Forest and its amici attempt to justify certiorari by arguing that the decision below created "tension" with other lower court rulings in failing to attribute Caraco's injury to (1) Forest's "mandatory compliance" with Hatch-Waxman, and (2) Ivax, the first filer, whose 180-day exclusivity period must run before Caraco reaches market. Pet. 16, 26-28; Ivax Br. 5-6, 10.

As shown below, however, the Act requires listing patents in the Orange Book only as a condition of receiving statutory benefits that depend on the validity and scope of those patents. Thus, it is misleading to portray the listing requirement as "mandatory." Furthermore, although the scope of Caraco's injury may be *worsened* by Ivax's 180 days of market exclusivity, it is not limited to—and does not depend on—the 180-day delay. If Caraco's product does not infringe Forest's patents, the listing of those patents *independently* causes market delay—potentially several years' worth of delay—that itself supports standing.

A. Forest's assertion that listing its patents in the Orange Book was "mandatory" mischaracterizes the Hatch-Waxman Act.

1. Like its first, Forest's second question presented—whether causation is satisfied where the injury "traces to a patent holder's compliance with a mandatory patent listing obligation" (Pet. i)—depends on a mischaracterization of the Act.

As Forest well knows from litigation over its own strategic choice *not* to list its patents in the Orange Book, the FDA's Orange Book-listing responsibilities are purely "ministerial."[6] It was Forest that took the initiative to obtain patent protection for Lexapro®, and Forest that drafted patents purportedly covering the market. Forest was thereafter "mandated" to list those patents in the Orange Book only if it wished to avail itself of Hatch-Waxman's mechanism for enforcing its monopoly—a mechanism that provides name-brand drug manufacturers substantially more protection than that enjoyed by patentees in any other context. The lawful availability of this statutory benefit (and of Forest's monopoly), however, depends on the validity and scope of the underlying patents. See 21 U.S.C. § 355(b)(1). Thus, it is misleading to say that Caraco's injury "traces to sovereign legal action," or that the decision below conflicts with lower court decisions addressing whether "but-for causation [is] sufficient to establish standing where ... the complained of conduct leads to injury only by virtue of its combination with other, more dominant causes traceable to sovereign acts." Pet. 16, 26. In sum, Forest has greatly overstated the sovereign's role in Orange Book listings and greatly understated its own.

2. Forest nonetheless attempts to gin up a conflict to support certiorari. But the two cases on which it relies (Pet. 26-27) involve highly dissimilar facts, and neither conflicts with the ruling below.

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[6] Pet. 6; see *Alphapharm Pty Ltd.* v. *Thompson*, 330 F. Supp. 2d 1 (D.D.C. 2004) (discussing Forest's strategic omission of a patent from its Orange Book-listing, rejecting an ANDA filer's complaint that the FDA was required to police such listings, and collecting authorities holding that the FDA has only a "ministerial role" in patent listings).

In *Bronson* v. *Swensen*, 500 F.3d 1099 (10th Cir. 2007), the plaintiffs attempted to challenge a criminal ban on polygamy by suing a county clerk for refusing to license a polygamous union. But as Forest notes (at 26), the plaintiffs there argued that they would have been immune from prosecution if the clerk issued them a marriage license, and the court rejected their argument because it turned on "collateral benefits" that they hoped to receive if the clerk acted in the future, rather than any injury the clerk's actions had already caused. See 500 F.3d at 1111. Here, by contrast, Caraco is suing Forest for actions it has already taken (listing its patents in the Orange Book), and injury it has already caused (throwing up a barrier to the market for generic Lexapro®). Moreover, the fact that a ruling for Caraco will have the incidental effect of triggering Ivax's 180-day exclusivity period does not diminish the fact that it will eliminate the barrier to market caused directly by Forest's patents. Thus, even setting aside the obvious factual differences between the decisions, *Bronson* does not conflict with the decision below.

Forest also asserts a conflict with *Fulani* v. *Brady*, 935 F.2d 1324 (D.C. Cir. 1991). There, a candidate excluded from a presidential debate sued the IRS to revoke the tax-exempt status of the debate's sponsor (who was not before the court), seeking to prevent it from holding the debate. See Pet. 27. But in denying standing, the court relied on the "special problems attendant upon the establishment of standing in . . . tax cases, when a litigant seeks to attack the tax exemption of a third party." 935 F.2d at 1327 (internal quotation marks omitted). Such "special problems" are absent here.

Fulani also held that intervening causes broke the chain connecting the IRS to the plaintiff's injury because, even if the court had revoked the sponsor's tax exemption, other factors still would have excluded the plaintiff from the debate. See 935 F.2d at 1329-1330. Here, by contrast, Forest's patent listing "creates an *independent* barrier to the drug market that deprives Caraco of an economic opportunity to compete," and "[i]t is well established that the creation of such barriers to compete satisfies the causation requirement." Pet. App. 27a (emphasis added).[7] Indeed, *Fulani* cuts *against* Forest's position: the court there refused to attribute causation to the sovereign when conduct by others—*parties akin to Forest*—was the true cause of injury. 935 F.2d at 1331.

3. At bottom, Forest's complaint with the Federal Circuit's traceability analysis has nothing to do with the legal standard applied by the decision below—the "but for" causation standard set forth in *Duke Power Co.* v. *Carolina Envt'l Study Group, Inc.*, 438 U.S. 59, 74 & n.26 (1978). See Pet. App. 26a. Instead, Forest is dissatisfied with how the court applied this settled principle in the Hatch-Waxman Act context. Even if Forest were correct on the merits, such an argument would not justify certiorari. But as we have shown, the court below faithfully applied this Court's jurisprudence.

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[7] Pfizer argues (at 17-18) that the decision below conflicts with *Prasco, LLC* v. *Medicis Pharm. Corp.*, 537 F.3d 1329 (Fed. Cir. 2008). But that argument depends on a flawed analogy between marking a product to provide statutory notice to potential infringers (which the *Prasco* plaintiff did *not* claim "had actually restrained its right to freely market [its product]," *id.* at 1339), and an Orange Book-listing (which immediately "creates an independent barrier to the drug market," Pet. App. 27a).

B. Caraco's injury is not limited to, and does not depend upon, the first filer's 180-day exclusivity period.

Forest and amicus Ivax also seek to justify review by arguing that the decision below created a conflict concerning the traceability standard in failing to trace Caraco's injury to Ivax's first-filer status, which they deem an "intervening cause." Pet. 16, 28; Ivax Br. 9-16. This argument lacks merit.

1. Although Caraco's ANDA may not be approved until Ivax's exclusivity period has run, that does not mean the exclusivity period is an intervening cause of Caraco's injury. Nor is this action "brought solely to spoil the first filer's exclusivity," as Pfizer asserts (at 19). To be sure, Caraco seeks to run off that 180-day delay, but also to avoid *years* of delay caused directly by the listing of Forest's patents. Whether Caraco is the first or last ANDA filer, it has a statutory right to file a CAPC challenging those patents. And a favorable ruling on Caraco's claims will clear both the (larger) barrier created by the listing of the patents and the (smaller) barrier created by the 180-day exclusivity period. In Congress's design, triggering the exclusivity period is simply an incidental effect of a successful challenge to the listed patents.

Even if the 180-day delay were not attributable to Forest's Orange Book-listing (which it is), the longer market delay caused by the listing of the patents is. For example, if Caraco defeated both the '712 and '941 patents in 2009, Caraco could enter the market in just 180 days—avoiding roughly *three years* of delay caused by the '712 patent, which otherwise would keep Caraco out of the market until 2012. This is independently sufficient to support standing.

2. Second, Ivax's argument—which acknowledges that Forest is a cause of Caraco's injury, but says "Ivax's intervening actions fundamentally sever the chain of causation"—assumes that a cause must be the *last* or *proximate* cause in the chain of causation to satisfy the causation requirement. Ivax Br. 5. But as this Court explained in *Bennett* v. *Spear*, 520 U.S. 154 (1997)—a case Forest and Ivax never cite—such a view "wrongly equates injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation." *Id.* at 168-169.

Forest's actions may not be the last step in the chain of causation, but they are an independent "but for" cause of Caraco's injury—which Forest does not deny. This is more than sufficient. As then-Judge Alito once observed, "Article III standing demands a 'causal relationship,' but neither the Supreme Court nor [the Third Circuit] has ever held that but-for causation is always needed," particularly "where an effect is 'causally over-determined,' *i.e.*, where there are multiple sufficient causes." *Khodara Envt'l, Inc.* v. *Blakey*, 376 F.3d 187, 195 (3d Cir. 2004).

3. In any event, the centerpiece of Ivax's argument that there is "deep and abiding confusion" in the circuit courts over the test for traceability (Br. 7, 11-13) is a stale conflict between the D.C. and Second Circuits over particular facts presented to both courts some twenty years ago. The D.C. Circuit in *Fulani* (discussed above) rejected the Second Circuit's analysis, which had found traceability because "but for" the IRS's actions, the plaintiff's exclusion from the debate ultimately would not have occurred. *Fulani* v. *League of Women Voters*, 882 F.2d 621, 628 (2d Cir. 1989). The D.C. Circuit concluded that the Second Circuit

overlooked intervening causes better viewed as the true causes of the plaintiff's harm. See 935 F.2d at 1328-1329. But this disagreement is limited to the cases' specific facts, and does not cast doubt on the legal principle applied below. Moreover, both cases pre-date *Bennett*, which confirms that a third party who proximately causes an injury is not the only party to whom that injury may constitutionally be traced. 520 U.S. at 168-169.

Nor have the Tenth and Eleventh Circuits "thrown up their hands" on the issue of traceability. Ivax Br. 13. Rather, as the cases cited by Ivax confirm, those courts have merely explained, correctly, that the causation requirement for standing is not as stringent as the concept of proximate cause. *Nova Health Sys.* v. *Gandy*, 416 F.3d 1149, 1156 (10th Cir. 2005); *Focus on the Family* v. *Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1273 (11th Cir. 2003).

In short, consistent with the decision below (Pet. App. 26a) and the position of *both* parties in this case (see Pet. 26), all the circuits recognize that an independent "but for" cause suffices to support standing. Accordingly, there is no conflict warranting certiorari.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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No. 08-624

IN THE
Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S,

Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF FOR THE PETITIONER

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January 21, 2009

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Any cognizable dispute underlying this case is dead. Plaintiff Caraco brought suit alleging a controversy over whether it infringed Forest's '941 patent. Forest then gave Caraco a covenant not to sue on that patent. That should have been the end of the matter. Article III justiciability does not exist where the underlying congressionally defined cause of action regarding infringement is unsustainable.

The Federal Circuit reached a different result only by reformulating the limited cause of action Congress actually created (one to resolve infringement disputes) into a new cause of action that Congress did not see fit to create (one to resolve disputes with Orange Book listing). Since Orange Book listing is mandatory under pain of criminal sanction (an uncontested point), the decision below is not only an affront to Article III, but an assault on core separation of powers principles defended by Article III. *Allen v. Wright*, 468 U.S. 737, 752 (1984). Only Congress can rewrite Hatch-Waxman.

Not only the legal stakes, but the economic and public health stakes of this case are enormous. None of the reasons Caraco offers to avoid review survives scrutiny. Indeed, Caraco never pointedly denies the immense significance of this case for preserving the balance of incentives for new drug innovation as against generic competition. The issues involved and the attestations of *amici* readily demonstrate that this case is one of exceptional importance.

Moreover, most cases involving Hatch-Waxman disputes cannot create circuit splits because of the Federal Circuit's exclusive jurisdiction over patent matters. Hence, it is a testament to the magnitude of the errors committed below that this Hatch-Waxman case fuels a number of more general splits

concerning Article III. Caraco's 34-page opposition launches mostly merits-based defenses, which, while rebutted below, are better tested in subsequent merits briefing.[1]

* * * *

Caraco argues that Forest cannot obtain *certiorari* because Forest conceded (i) CAPC actions reach to full constitutional limits; and (ii) Forest's listing of the '941 patent in the Orange Book is a "but for" cause of alleged injury. Opp. 12. The first purported concession establishes nothing, and the second was never conceded. Actions under the Declaratory Judgment Act are similarly coextensive with Article III's limits. *See* 28 U.S.C. § 2201(a) ("actual controversy"). The question here is whether the grant of a covenant not to sue takes this case beyond Article III. In terms of the causation element of standing, Forest plainly contended that Orange Book listing cannot be a basis for asserting injury against Forest because listing is mandated by Congress. Pet. 6-7, 25-31.

Caraco asserts that because Forest's arguments require consulting the text of Hatch-Waxman, they are "statutory arguments," and hence fall outside the Article III questions presented. Opp. 12-13, 15, 18.

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[1] In one of its rare, non-merits points, Caraco calls this petition interlocutory. Opp. 1. But cases where review is urged regarding rulings on motions to dismiss fall into a category of cases the Court frequently accepts. For instance, in *Allen*, the Court reviewed the D.C. Circuit's reversal of a dismissal on standing grounds. *See also* Eugene Gressman, et al., SUPREME COURT PRACTICE, § 4.18, at 281-82 (9th ed. 2008) (collecting other such cases).

But even if the Federal Circuit's statutory misconstructions were not fairly encompassed within Forest's questions (which they are), no rule holds that constitutional standing questions must be evaluated without resort to statutory construction concerning the cause of action at issue. *International Primate Protection League v. Administrators of Tulane Educ. Fund*, 500 U.S. 72, 77 (1991).

A. Caraco's Arguments Defending Actionable Injury in Fact

1. Forest never contended that the civil action to obtain patent certainty ("CAPC") authorized only first ANDA filers to bring declaratory actions against patentees. Caraco's suggestion that Forest's petition rests on such a contention (Opp. 1-2, 13, 15) is a straw man and provides no basis for sustaining the decision below. The simple fact is that the Federal Circuit took a cause of action designed to resolve validity and infringement disputes and contorted it into a cause of action premised on injury from Orange Book listing decisions. App. 26a-27a.

The terms Caraco uses in defining CAPC actions are themselves revealing. According to Caraco, the cause of action is not one to resolve infringement disputes, but one designed to vindicate its supposed "*right to a ruling* on whether its product infringes valid Orange Book-listed patents." Opp. 16 (emphasis added). Countenancing freestanding "rights to rulings" (though not what Congress created here) would eviscerate Article III.

2. From there, Caraco argues that Forest merely assumes that CAPC suits can do no more than resolve infringement disputes. Opp. 14-16. This

argument fails under the plain text: "[T]he applicant . . . may . . . bring a civil action . . . against the owner or holder . . . for a declaratory judgment that the patent is invalid or will be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II). Orange Book listing injuries are not made actionable.

3. Caraco heavily flavors its opposition with claims that Forest is "gaming" Hatch-Waxman. Opp. 19. The claims are unsupportable. Forest took only two actions that the Federal Circuit or Caraco have pointed to as potentially causing Caraco's alleged injury: (i) listing the '941 patent in the Orange Book, and (ii) granting Caraco a covenant not to sue. Neither represents gaming. To reiterate, Orange Book listing is mandatory, and failure to list can result in criminal penalties. Pet. 6-7, 29. Complying with a government mandate cannot possibly be labeled as gaming. Nor can granting a covenant not to sue. As the Federal Circuit conceded, "[i]f a threat of suit was the only action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case." App. 34a. In other words, granting the covenant was not "gaming," but legitimate action foreseeably leading to mootness.

4. The Federal Circuit's expansion of the rights of laggard ANDA filers would also make structural hash of the four-paragraph set of Hatch-Waxman certification options. As Caraco recognizes, beyond the paragraph IV certifications of Ivax and Caraco at issue here, ANDA filers can make paragraph I certifications. Opp. 3 (paragraph I, in Caraco's own words, is "a statement that *the required information* relating to the patent has not been filed with the

FDA") (emphasis added). Therefore, the very concept of a paragraph I certification would make no sense if Orange Book listing were not mandatory. *Astoria Fed. Sav. & Loan Ass'n. v. Solimino*, 501 U.S. 104, 112 (1991) ("we construe statutes, where possible, so as to avoid rendering superfluous any parts thereof").

5. Caraco tries to take back what the Federal Circuit conceded (without Orange Book listing, Forest's covenant would have mooted this case) by arguing that Forest was somehow obligated not just to promise not to sue, but to go further and concede noninfringement. Opp. 17-19 & n.4. This is against all reason. Cases can be settled and thus mooted (and frequently are) without one side entirely capitulating to the demands of its opponent. Nothing in Hatch-Waxman requires Forest to enter into a stipulation or consent decree finding noninfringement.

6. Relying on Senator Kennedy standing alone, Caraco argues that Congress was troubled by covenants not to sue when it amended Hatch-Waxman in 2003 through the "MMA." Opp. 5-6. That effort falters because Congress could have regulated or restricted such covenants, but did not (despite making other adjustments to exclusivity rights for first filers). Indeed, Caraco ignores the Federal Circuit's attempt to bury Senator Kennedy's caveat that, for Article III reasons, the new CAPC action may not operate against such covenants. Pet. 13-14. Judge Friedman highlighted this caveat. App. 42a.

7. Despite paying lip service to the balance struck in Hatch-Waxman between incentivizing innovation and price reduction, Opp. 2, Caraco seeks

to prop up the Federal Circuit's rebalancing of those statutory policies, which failed to honor the three distinct phases created by the statute:

Phase I:	A period of monopoly for the pioneer.
Phase II:	A duopoly period where the pioneer and the first ANDA filer share exclusivity.
Phase III:	A period where the pioneer and all ANDA filers compete on equal footing.

CAPC actions are the gateway between Phases I and II to Phase III. But there is no statutory indication that the economic returns Forest obtains under Phases I and II may be cut short by ignoring the limits of CAPC actions as set against Article III. As is clear from Caraco's five citations (Opp. 4, 5, 6, 8) to Judge Gajarsa's (not Judge Dyk's) dissent from denial of rehearing *en banc* in *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 405 F.3d 990 (Fed. Cir. 2005), what the Judges sympathetic to Caraco rely on to establish standing are not actions by the pioneer, but policy fears for laggard generics given "th[e] bottleneck under the statute." *Id.* at 994 (Gajarsa, J., dissenting). That, however, is a disagreement with Congress.

8. Caraco then turns for support to *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), Opp. 19-20, where the D.C. Circuit suggested that later ANDA filers sometimes "buil[d] a better mousetrap." *Id.* at 1073. But *Mova* was issued *before* the MMA amended Hatch-Waxman. In the MMA, Congress itself carefully balanced the incentives it wanted to create for pioneers, first ANDA filers, and later ANDA filers. Pre-MMA

musings in D.C. Circuit *dicta* are unavailing.

9. In an attempt to turn the MMA's advent to its side, Caraco argues that this case is a "relic." Opp. 14, 20-21. Untrue. The Federal Circuit majority was quite clear that its holding will apply equally to the pre- and post-MMA regimes. App. 10a n.4 ("under *both* . . . *provisions*, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed") (emphasis added). *See also* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (post-MMA judgment trigger serving same basic function as pre-MMA judgment trigger in 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000)); WLF Br. 12, 22 & n.10.

10. Forest argues that the circuits are in conflict over whether a "legally protected right" is a precondition to demonstrating injury-in-fact. Pet. 17-25. Caraco provides no response, except to assert that *MedImmune* controls. Opp. 22-23. But that case does not even involve Hatch-Waxman.

Caraco argues that because *MedImmune* found standing regarding a licensing dispute, and because a patent license is an "enforceable covenant not to sue," Opp. 22-23, *MedImmune* controls. But even the Federal Circuit panel did not make that claim. The panel maintained only that *MedImmune* required testing for case or controversy under the totality of circumstances. App. 22a.

MedImmune is perfectly consistent with this petition. All *MedImmune* holds is that a licensee can make licensing payments under protest without surrendering its ability to challenge the license's applicability in the first place. As section II of

MedImmune crystallizes, the licensee had a valid cause of action under a common law contract theory. 549 U.S. at 123-25. Here, there is no contract between Caraco and Forest. Caraco's only cause of action is a statutory one concerning whether it infringed the '941 patent. Justiciability was not destroyed by the license in *MedImmune*, *compare* Opp. 23, because that dispute centered on the license's applicability. Here, the terms and effect of the covenant are not in dispute.[2]

11. Caraco also tries to evade the point that the Federal Circuit's covenant-not-to-sue cases are confused by arguing that all such cases predate *MedImmune*. Opp. 24. But the Federal Circuit's decision in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007) (allowing covenant to create mootness), post-dates *MedImmune*. Indeed, the *Benitec* panel called for supplemental briefing on *MedImmune*. Moreover, Judge Dyk's dissent deplored the confusion. *See id.* at 1354 ("The majority's decision here is not only inconsistent with the Supreme Court precedent; it exposes an inconsistency in this court's own jurisprudence.").

12. Finally, Caraco attempts to duck the confusion engendered by *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008) (holding covenant mooted CAPC dispute). Opp. 25-26. Winston & Strawn (Caraco's counsel here),

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[2] *MedImmune* also makes clear that its outcome may have been different if there had been a separate waiver of the licensee's ability to seek contract relief. 549 U.S. at 125. Hence, Forest's waiver of its *only* right—to sue for infringement—also sets this case apart from *MedImmune*.

however, has elsewhere acknowledged that it reads *Janssen* to mean that "*possible future delay by a first Paragraph IV ANDA filer* in launching its generic product does not harm a second Paragraph IV ANDA filer sufficiently to create a case or controversy."[3]

This raises the issue of ripeness—the heart of Judge Friedman's dissent.[4] On that score, Caraco does not contest *amicus* WLF's observation that the most likely outcome here is that, even if the decision below is allowed to stand, the earliest Caraco could enter the market for Lexapro® is *180 days after* the expiration of the '712 patent *in 2012*. WLF Br. 20.

B. Caraco's Arguments Defending Causation

1. Caraco argues that Forest only had to list the '941 patent if it wanted to claim Hatch-Waxman's exclusive-marketing benefits. Opp. 13, 27. This ignores: (i) Caraco's failure to answer Forest's point that the failure to list can bring criminal sanctions, Pet. 29; and (ii) Caraco's failure to counter Ivax's point that bad faith listing decisions can bring antitrust liability, Ivax Br. 20-21.

2. Caraco also seizes on the word "ministerial" to describe the listing obligation, as if that term meant an insubstantial obligation that cannot constitute an intervening cause of Caraco's alleged injury. Opp. 3,

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[3] Patent Decision Summaries, http://www.winston.com/siteFiles/publications/FedCircSumVol1,Issue19.html (emphasis added).

[4] Caraco attempts to neutralize Judge Friedman's dissent by listing points Judge Friedman did not speak to, as if that means he agreed with Caraco. Opp. 11-12.

28 (accusing Forest of mischaracterizing Hatch-Waxman). But as a matter of basic administrative law, the term "ministerial" reinforces, rather than undermines, the need for Orange Book listing. *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (ministerial duties are "non-discretionary act[s]"). Cases holding that the listing obligation is ministerial mean the FDA has no choice but to list patents identified by innovators. *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001). Neither do such innovators have any listing discretion.[5]

3. Although it failed to challenge the existence of the circuit split Forest identified to support its first question presented, Pet. 17-19 & nn. 8-9, Caraco does attempt to rebut the existence of a relevant circuit split on the second question. Opp. 29-30. Beginning with *Bronson v. Swensen*, 500 F.3d 1099 (10th Cir. 2007), Caraco says that case is inapposite because the actions of the county clerk had not yet caused any injury, whereas Forest's listing decision has already caused injury. Opp. 29. In reality, however, Forest's Orange Book listing has also not yet caused Caraco any injury. This was a lynchpin of Judge Friedman's dissent. App. 40a.

4. Caraco argues that *Fulani v. Brady*, 935 F.2d 1324 (D.C. Cir. 1991), is inapplicable because it rested on special standing rules in tax cases. Opp. 29. The analysis in *Fulani* to which Forest pointed,

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[5] Caraco argues that *Alphapharm Pty. Ltd v. Thompson*, 330 F. Supp. 2d 1 (D.D.C. 2004), found Forest to have improperly listed a patent. Opp. 28 n.6. That *non sequitur* was never tested on the merits and Forest denies it.

however, is not unique to tax cases. *See id.* at 1328-31. Moreover, there is no standing rule that cordons tax cases off as untouchable precedent in non-tax cases. *See, e.g.*, *Sprint Commc'ns. Co. v. APCC Servs., Inc.*, 128 S. Ct. 2531, 2535 (2008) (non-tax standing case citing tax standing case of *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332 (2006)).[6]

5. Caraco is also incorrect that Forest is simply challenging the *application* of *Duke Power Co. v. Carolina Envt'l Study Group, Inc.*, 438 U.S. 59, 74 (1978). Caraco proceeds as if *Duke Power* embodies all Supreme Court standing jurisprudence. Caraco ignores the discussion of how the decision below conflicts with *Lujan*, *Allen*, *Simon*, and *Warth*. Pet. 27-28.

6. Caraco claims that it is not circumventing Ivax's 180-day exclusivity because overcoming that period is merely the fringe benefit of Caraco exercising its right to challenge Forest's Orange Book listing. Opp. 31. This argument falters on the same point as Caraco's entire case—there is no such Orange Book cause of action. *Supra* 3.

7. Finally, Caraco claims on the merits that Forest's causation analysis runs afoul of *Bennett v. Spear*, 520 U.S. 154 (1997). Not so. In *Bennett*, holders of water rights challenged a Fish and Wildlife Service ("FWS") determination effectively

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[6] Caraco suggests that a split between the D.C. Circuit's *Fulani* decision and another case involving candidate Fulani in the Second Circuit is "stale." Opp. 32. This ignores that Forest posited a split between the decision below and *Fulani plus Bronson*, and never mentioned the Second Circuit case.

redirecting privately owned water to endangered suckerfish. The government protested that the Bureau of Reclamation (also part of the Interior Department) *might* choose not to follow the FWS determination, thereby interrupting causation. This Court rejected that defense, noting that there was no "*independent*" break in the causal chain, *id.* at 169, especially where the FWS determination had "virtually determinative effect," *id.* at 170, and was thus the predominant cause of the private injuries. Here, the actions of Congress in mandating Orange Book listing are neither attributable to Forest, nor those of a mere sister sub-agency.[7]

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[7] Caraco also cites *Khodara Environmental, Inc. v. Blakey*, 376 F.3d 187, 195 (3d Cir. 2004) (Alito, J.). *Khodara* holds that there can be multiple actionable causes of an alleged injury, but only where "there are multiple sufficient causes." Here, as the Federal Circuit admitted, there is but one supposedly sufficient cause—Orange Book listing.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for writ of certiorari.

Respectfully submitted,

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FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S,

Petitioners,

v.

CARACO PHARMACEUTICAL LABOR TORIES, LTD.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF IVAX PHARMACEUTICALS, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTIONS PRESENTED

(I) Whether the Federal Circuit erred, and deepened confusion among the lower courts, by holding that a declaratory-judgment plaintiff can establish traceability for purposes of Article III standing simply by alleging "but-for" causation between some action or conduct by the defendant and the plaintiff's asserted injury.

(II) Whether the Federal Circuit erred by holding that a declaratory-judgment plaintiff has standing where the plaintiff's complaint does not challenge the legality of the particular action or conduct alleged to have caused the plaintiff's asserted injury.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Ivax Pharmaceuticals, Inc. hereby states that it is a direct, wholly-owned subsidiary of Ivax Corporation, which is, in turn, wholly owned through the following chain: Teva Pharmaceuticals USA, Inc., Orvet UK Unlimited, Teva Pharmaceuticals Europe B.V., then Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded parent company of Ivax Pharmaceuticals, Inc. and no publicly-traded company owns more than 10 percent of its stock.

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STATEMENT OF INTEREST[1]

Ivax Pharmaceuticals, Inc. ("Ivax") holds tentatively approved Abbreviated New Drug Application ("ANDA") No. 76-765 for generic escitalopram oxalate tablets ("EO") in 5-, 10-, and 20-mg dosages. Because Ivax was the first generic EO applicant to challenge petitioner Forest's U.S. Patent No. 6,916,941 ("the '941 patent"), Ivax is entitled to a 180-day period of marketing exclusivity for generic EO under 21 U.S.C. § 355(j)(5)(B)(iv).[2]

As the court below recognized, respondent Caraco's declaratory judgment action — which requests a judgment that its EO products do not infringe the '941 patent, even though petitioner Forest has covenanted never to assert the '941 patent against Caraco — seeks to trigger Ivax's marketing exclusivity before Ivax ever has an

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[1] All parties have consented to the filing of this brief, and letters evincing such consent have been filed with the Clerk. Pursuant to this Court's Rule 37.6, *amicus* states that no attorney for a party authored any part of this brief and that neither such attorney, nor any party, nor any person or entity other than *amicus*, its members, or its attorneys made a monetary contribution intended to fund the preparation or submission of this brief.

[2] This statute was enacted as part of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). This legislation is commonly referred to as the "Hatch-Waxman Act," as Ivax will refer to it in this brief.

opportunity to take advantage of that statutory reward. Pet. App. 28a ("A favorable judgment in this case would clear the path to FDA approval that Forest's actions would otherwise deny Caraco — namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) to activate Ivax's exclusivity period."). Ivax has a clear interest in preserving its legal entitlement to marketing exclusivity, and, thus, in the outcome of this case.

This case also presents recurring issues that are likely to have a significant long-term impact on Ivax's business, the generic pharmaceutical industry as a whole, and the federal courts. When Congress amended the Hatch-Waxman Act to create what it called a "civil action to obtain patent certainty," 21 U.S.C. § 355(j)(5)(C), this case decidedly was not what it had in mind. As the terminology employed by Congress suggests, that provision was intended to reduce delays in the resolution of *genuine* patent disputes between pharmaceutical manufacturers because Congress recognized that patent *un*certainty itself often deters the launch of generic drugs — even of generic drugs that have received FDA approval. *See Teva Pharms. USA, Inc. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342-44 (Fed. Cir. 2007).

Caraco, however, faces no patent uncertainty in this case, because Forest's covenant not to assert the '941 patent means both that Caraco's FDA approval is not blocked by that patent *and* that Caraco faces no conceivable patent liability for launching its EO products. As a result, the decision below threatens to burden the courts with contrived patent infringement cases and, thus, to delay the resolution

of genuine patent disputes like the many in which Ivax currently is involved.

But the decision below will do far more than permit litigants to clog the federal courts with unnecessary claims. It will fundamentally undermine one of the Act's most important features: 180 days of marketing exclusivity for the first generic applicant to challenge a pharmaceutical patent that otherwise would block the introduction of generic competition. When Congress enacted the statute, it deliberately chose to reward that first generic applicant with a period of marketing exclusivity in order to encourage generic companies to undertake the significant expense associated with developing a generic product and to assume the risks associated with high-stakes patent litigation. *See, e.g., Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008) ("The 180-day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company a period to recover its investment in these challenges."). The appellate court's decision in this case, however, encourages subsequent generic applicants to knock out the first-filer's exclusivity by challenging a patent that the brand manufacturer has (validly and enforceably) pledged never to assert against the subsequent generic applicant.

This Court thus should have no illusions about the consequences of the panel's decision. If generic companies can bring declaratory judgment actions directed at patents that cannot be enforced against them, and by so doing eliminate a competitor's marketing exclusivity, they will do so at every

opportunity. That not only will undercut the statutory incentive scheme by rendering the 180-day exclusivity period vulnerable to manipulative patent litigation by third parties — reducing the incentive for generic manufacturers to file paragraph IV certifications in the first place, and thereby slowing the onset of generic competition over the long run — but also will flood the courts with burdensome patent cases where nothing is at stake because the patents-in-suit never will (and never can) be asserted against the plaintiff that challenges them. Beyond its specific interest in this case, then, Ivax has a strong interest in protecting the exclusivity incentive against unproductive, self-serving, and shortsighted challenges like Caraco's.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The Federal Circuit's decision in this case stretches the boundaries of Article III beyond the breaking point, and opens the door to contrived litigation over questions not genuinely in dispute. In the process, the Federal Circuit contributed to the lower courts' deep and abiding confusion over this Court's standing jurisprudence, and took aim at one of the most important features of the Hatch-Waxman Act — the 180-day period of marketing exclusivity awarded to the first generic drug applicant that challenges a brand-manufacturer's pharmaceutical patents.

If left intact, the appellate court's overly expansive view of Article III jurisdiction would undermine a statutory incentive that many believe to be responsible for *hundreds of billions of dollars* in healthcare savings over the past two decades, with

dire consequences for the *millions of patients* who depend on safe and affordable generic medications to treat their illnesses. While the broad jurisdictional implications of the Federal Circuit's decision would warrant this Court's review in their own right, the fact that they arise in this particular context makes review in this case imperative.

The issues raised by the Federal Circuit's decision cut to the heart of the Constitution's standing requirements. First, the appellate court erred, and in the process deepened confusion among the lower courts, by holding that mere but-for causation between a defendant's actions and the plaintiff's asserted injuries invariably suffices to establish the "traceability" requirement of Article III standing. In particular, the Federal Circuit held in this case that Caraco's asserted injury — namely, that Ivax's statutory right to marketing exclusivity temporarily bars FDA from approving Caraco's ANDA — was sufficiently "traceable to Forest" because Forest's decision to list the '941 patent in FDA's official list of drug-claiming patents (the "Orange Book") gave Ivax the chance to garner the allegedly injurious exclusivity period by filing the first patent-challenging "Paragraph IV" certification to the '941 patent. Pet. App. 26a (capitalization omitted).

The problem with that analysis is that Ivax's intervening actions fundamentally sever the chain of causation between Forest's initial patent-listing decision and Caraco's asserted injury. After all, as the Federal Circuit itself recognized, Caraco is "injured" by Ivax's statutory exclusivity period *only* because Ivax, which is not a party to this case, filed the first Paragraph IV certification to the '941 patent

(Caraco was *seventh*). Pet. App. 16a, 19a-20a. Had *Caraco* filed the first Paragraph IV certification to the '941 patent instead of sitting on its rights, Forest's patent-listing decision would not have injured Caraco at all; instead, Caraco would have earned the very exclusivity period about which it complains.

The appellate court, however, held that that clear break in the causal chain between Forest's allegedly-injurious conduct and Caraco's asserted injury was constitutionally irrelevant simply because Forest's initial decision to list the '941 patent was a "but-for cause" of Caraco's asserted injury. Pet. App. 26a ("Such but-for causation is sufficient to satisfy the traceability requirement of Article III standing.") (citing *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26 (1978)).

That was error. Indeed, this Court long has held that — even where a defendant's actions contribute to a plaintiff's injury — the plaintiff lacks standing where the asserted "injury ... results from the independent action of some third party not before the court." *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976); *Warth v. Seldin*, 422 U.S. 490, 504-05 (1975). That, of course, perfectly describes what happened in this case: Caraco's injury results only from Ivax's independent filing of the first Paragraph IV certification to the '941 patent (and then only because Forest also covenanted not to sue Caraco for infringing the '941 patent).

Even so, the Federal Circuit's confusion is in some respects understandable. Notwithstanding this Court's decisions in *Simon* and *Warth*, several appellate courts have (just like the Federal Circuit in

this case) misread subsequent decisions by this Court to hold that mere but-for causation is all that standing's "traceability" requirement demands. *See, e.g., The Pitt News v. Fisher*, 215 F.3d 354, 361 (3d Cir. 2000); *Fulani v. League of Women Voters Educ. Fund [Fulani I]*, 882 F.2d 621, 628 (2d Cir. 1989).

The result is a three-way circuit split, with some courts holding that but-for causation is all that's necessary to establish traceability (*e.g.*, the Second Circuit in *Fulani I*, the Third Circuit in *Pitt News*, and the Federal Circuit in this case); some holding that mere but-for causation is not alone sufficient to establish traceability (*e.g.*, the D.C. Circuit in *Fulani v. Brady [Fulani II]*, 935 F.2d 1324, 1329 (D.C. Cir. 1991) and *Shoreham-Wading River Cent. School Dist. v. U.S. Nuclear Regulatory Comm'n*, 931 F.2d 102, 105 (D.C. Cir. 1991)); and still others holding that "something" between but-for causation and proximate cause is required (*e.g.*, the Tenth Circuit in *Nova Health Sys. v. Gandy*, 416 F.3d 1149, 1156 (10th Cir. 2005), and the Eleventh Circuit in *Focus on the Family v. Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1273 (11th Cir. 2003)).

This case thus offers an excellent opportunity to resolve the lower courts' deep and abiding confusion over the proper test for establishing traceability under Article III by affirming the bedrock principle that traceability cannot be shown where the plaintiff's "injury ... results from the independent action of some third party not before the court," whether or not some prior action by the defendant is a but-for cause of that injury. *Simon*, 426 U.S. at 41-42.

Even if the lower courts were not hopelessly confused over whether but-for causation is sufficient to establish traceability, review still would be warranted here because the Federal Circuit further erred by holding that a declaratory-judgment plaintiff has standing even though the plaintiff's complaint does not actually challenge the legality of the particular action or conduct alleged to have caused the plaintiff's asserted injury. As set forth above, the Federal Circuit held that Caraco had standing to pursue this action against Forest solely because Forest's decision to list the '941 patent in FDA's Orange Book eventually contributed to Caraco's asserted injury — namely, the fact that Ivax's statutory exclusivity (which is based on the '941 patent) temporarily will keep Caraco off the market.

The key point here, however, is that Caraco's complaint does not remotely allege (much less seek a judgment) that Forest's decision to list the '941 patent in FDA's Orange Book was itself unlawful, illegitimate, or otherwise improper. Instead, Caraco's complaint merely seeks a declaratory judgment that its proposed generic EO products *would not infringe* the '941 patent. That question is fundamentally distinct from the issue of whether Forest properly listed the '941 patent in the Orange Book; indeed, the question of whether a generic applicant's drug products would infringe a listed patent has no bearing at all on whether the brand-name manufacturer properly listed that patent in the first place.

As a result, the Federal Circuit's decision squarely conflicts with a long line of cases holding

that the plaintiff's asserted injury must be based on "the defendant's *allegedly unlawful conduct*" in order to ground standing under Article III. *Allen v. Wright*, 468 U.S. 737, 751 (1984) (emphasis added); *see also Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

That requirement is no mere technicality: it is the essential prerequisite to an Article III case or controversy. After all, the Framers did not establish a federal Judiciary to remediate concededly lawful injuries; they established the federal courts to redress alleged legal wrongs. The Federal Circuit's contrary approach effectively writes the case-or-controversy requirement out of the Constitution, and effectively will require already-overburdened district courts to busy themselves rendering the very sort of advisory opinions that this Court has long foresworn.

The petition should be granted, and the Federal Circuit's decision reversed.

REASONS FOR GRANTING THE WRIT

I. The Federal Circuit Erred, And Deepened Confusion Among The Lower Courts, By Holding That A Declaratory-Judgment Plaintiff Can Establish Traceability For Purposes Of Article III Standing Simply By Alleging "But-For" Causation Between Some Action Or Conduct By The Defendant And The Plaintiff's Asserted Injury.

The Federal Circuit erred, and deepened confusion among the lower courts, by holding that a

declaratory-judgment plaintiff can establish traceability for purposes of Article III standing simply by alleging "but-for" causation between some action or conduct by the defendant and the plaintiff's asserted injury. Indeed, this Court held nearly thirty years ago that Article III standing "requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, *and not injury that results from the independent action of some third party not before the court.*" *Simon*, 426 U.S. at 41-42 (emphasis added); *see also Lujan*, 504 U.S. at 560-61 ("[T]here must be a causal connection between the injury and the conduct complained of — the injury has to be 'fairly traceable to the challenged action of the defendant, *and not the result of the independent action of some third party not before the court.*'") (quoting *Simon*; alterations omitted; emphasis added).

That perfectly describes what happened in this case. Caraco's asserted injury — its inability to secure immediate FDA approval as a result of Ivax's statutory exclusivity period — can be traced back to Forest's initial patent-listing decision *only* because third-party Ivax challenged Forest's listed patents before any other applicant and thereby earned 180-day exclusivity under the Hatch-Waxman Act. Accordingly, Caraco's injury unquestionably "results from the independent actions of some third party not before the court," and Caraco thus lacks standing to pursue its declaratory claims against Forest. *Simon*, 426 U.S. at 41-42; *Ne. Fla. Chapter of Ass'd Gen. Contractors of Am.*, 508 U.S. 656, 663 (1993) ("[A] party seeking to invoke a federal court's jurisdiction must demonstrate ... a causal relationship between the injury and the challenged conduct, by which we

mean that the injury fairly can be traced to the challenged action of the defendant, *and has not resulted from the independent action of some third party not before the court.*") (internal quotation omitted) (emphasis added).

The Federal Circuit nonetheless held that Caraco's injury was sufficiently traceable to Forest simply because Forest's initial decision to list the '941 patent was a "but-for cause" of Caraco's asserted injury, and "[s]uch but-for causation is sufficient to satisfy the traceability requirement of Article III standing." Pet. App. 26a (citing *Duke Power*, 438 U.S. at 74-78, 81 n.26). That holding lays bare the deep and abiding confusion among the lower courts over this Court's standing jurisprudence, and, in particular, over the strength of the causal connection that must be shown between a defendant's actions and the plaintiff's asserted injury in order to demonstrate traceability for purposes of Article III standing. The Federal Circuit's simplistic holding on this point — that "but-for" causation is all that Article III's "traceability" requirement demands — is not faithful to this Court's precedents, and directly conflicts with the decisions of other circuit courts.

Indeed, the Federal Circuit's holding on this point exacerbates a three-way split between the lower courts on precisely this point. The Second and Third Circuits have held — like the Federal Circuit here — that but-for causation alone suffices to establishes traceability for purposes of Article III's standing requirement. *See The Pitt News*, 215 F.3d at 360-61 ("We ... conclude that the injury alleged ... is fairly traceable to the enforcement of [the challenged law]. To analogize this situation to a familiar example in

tort law, the enforcement of [the challenged statute] was the cause-in-fact of the financial impact felt by [plaintiff]. 'But for' this enforcement, its advertisers would not have canceled their contracts."); *Fulani I*, 882 F.2d at 628 ("*But for* the government's refusal to revoke the [private defendant's] tax-exempt status, then, [the private defendant], as a practical matter, would have been unable to sponsor the allegedly partisan debates which caused the injury of which [plaintiff] complains. [W]e conclude that there is a nexus between the federal defendants' tax treatment of the [private defendant] and [plaintiff]'s asserted injuries which enables [plaintiff] to trace her injury directly back to such federal defendants' tax treatment of the [private defendant]."") (emphasis in original).

On the other hand, the D.C. Circuit squarely has rejected the proposition (and *expressly* disagreed with its sister circuits) that but-for causation alone is sufficient to demonstrate traceability where there are "intervening causal factors." *See, e.g.*, *Fulani II*, 935 F.2d at 1329 ("[In *Fulani I*] the Second Circuit granted [plaintiff] standing to challenge the [private defendant]'s tax-exempt status because '*but for* the government's refusal to revoke the League's tax-exempt status, the [private defendant] would have been unable to sponsor the allegedly partisan debates which caused the injury of which [plaintiff] complains' .... By taking [federal action] as a given, however, the Second Circuit ignores the fact that the alleged traceability and redressability may be found in [*Fulani I*] — and could be found in the present case — only in combination with significant intervening causal factors.") (quoting *Fulani I*); *see also Shoreham-Wading River Cent. Sch. Dist.*, 931

F.2d at 105 ("While the ban on refueling may be a 'but for' cause of any such future rulings and thus of any resulting risks, the exemptions themselves will be the operative causes. The link with the refueling ban is simply too remote."); *cf. Huddy v. F.C.C.*, 236 F.3d 720, 724 (D.C. Cir. 2001) ("We question whether 'but for' causation of this sort could ever be sufficient to confer constitutional standing.... It seems improbable that the Court intends all its learning on constitutional standing to be so readily evaded.").

Finally, the Tenth and Eleventh Circuits have essentially thrown up their hands and declared that "something" between but-for causation and proximate cause is required to show traceability. *See, e.g., Nova Health Sys.*, 416 F.3d at 1156 ("As other courts have noted, Article III's causation requirement demands something less than the concept of proximate cause. Yet Article III does at least require proof of a substantial likelihood that the defendant's conduct caused plaintiff's injury in fact.") (citing *Focus on the Family*, 344 F.3d at 1273; quotation omitted)).

In fairness to the lower courts, however, much of their confusion on this point stems from tension within this Court's own precedents on traceability — and, in particular, on this Court's decision in *Duke Power*. In that case, plaintiff environmental groups and residents of an area surrounding a proposed nuclear power plant brought suit against the Nuclear Regulatory Commission ("NRC") and the operator of a proposed nuclear power plant, seeking a declaratory judgment that the Price Anderson Act ("PAA") unconstitutionally limited the liability of nuclear operators and effectuated a "taking" of the

plaintiffs' property in violation of the Fifth Amendment. 438 U.S. at 69. To support those claims, plaintiffs alleged (among other things) that the proposed plant could not be constructed in the absence of the PAA's liability cap, and that the plant's operation invariably would emit low-level radiation that would harm the local environment and reduce surrounding property values. *Id.* at 73.

The *Duke Power* Court began its standing analysis by holding that plaintiffs' asserted injuries were legally cognizable. *Id.* at 73-74. But when the Court turned to the next prong of the standing analysis — traceability — it immediately conflated that requirement with redressability. "The more difficult step in the standing inquiry is establishing that these injuries 'fairly *can be traced* to the challenged action of the defendant,' or put otherwise, that the exercise of the Court's remedial powers *would redress* the claimed injuries." *Id.* at 74 (quoting *Simon*, 426 U.S. at 41) (emphasis added). It then agreed with the district court's factual findings and legal conclusion that *the latter test* — redressability — was satisfied because "Duke would not be able to complete the construction and maintain the operation of the [proposed plants] but for the protection provided by the [PAA]." *Id.* at 74-75 (quoting district court opinion); *id.* at 75 & n.20 ("These findings ... if accepted ... would likely satisfy the second prong of the constitutional test for standing as elaborated in *Simon*. Our recent cases have required no more than a showing that there is a 'substantial likelihood' that the relief requested *will redress the injury claimed to satisfy the second prong of the constitutional standing requirement.*") (citing *inter alia Simon*, 426 U.S. at 38; emphasis added).

Since *Duke Power*, of course, this Court has made clear that traceability and redressability are distinct requirements. *Steel Co.*, 523 U.S. at 106 n.7 ("[The dissent] also seems to suggest that redressability always exists when the defendant has directly injured the plaintiff. If that were so, the redressability requirement would be entirely superfluous, since the causation requirement asks whether the injury is 'fairly ... traceable to the challenged action of the defendant, and not ... the result of the independent action of some third party not before the court.'") (alterations omitted); *Allen*, 468 U.S. at 753 n.19 ("The 'fairly traceable' and 'redressability' components of the constitutional standing inquiry were initially articulated by this Court as 'two facets of a single causation requirement.' C. Wright, *Law of Federal Courts* § 13, p. 68, n. 43 (4th ed. 1983). [But] the former examines the causal connection between the assertedly unlawful conduct and the alleged injury, whereas the latter examines the causal connection between the alleged injury and the judicial relief requested. Cases such as this, in which the relief requested goes well beyond the violation of law alleged, illustrate why it is important to keep the inquiries separate.").

Yet *Duke Power*'s unclear approach continues to produce confusion among the lower courts, with some (including the court in this case) improperly applying *Duke Power*'s "but-for" redressability analysis in the course of assessing traceability and then ignoring the significance of intervening breaks in the causal chain. Indeed, this case perfectly illustrates the point. No one disputes that Caraco's injury would be redressed if it obtained a judgment that its proposed

EO products would not infringe Forest's '941 patent. After all, such a judgment would trigger Ivax's statutory exclusivity period, and once that 180-day period expires, Caraco would be free to enter the market. Pet. App. 27a-28a.

But the fact that litigation success will redress Caraco's asserted injury does not suffice to demonstrate the existence of a sufficiently traceable link between the plaintiff's injury and defendant's conduct. Instead, to reiterate, Caraco's asserted injury in this case was not caused in any meaningful sense by Forest's patent-listing decision; it was instead caused by the fact that Ivax beat Caraco to the punch, and thereby earned the allegedly injurious marketing exclusivity period by filing the first Paragraph IV certification to the '941 patent. Under these circumstances, Ivax's intervening actions fundamentally sever the link between Forest's patent-listing decision and Caraco's injury. Regardless of whether this suit might redress those injuries, Caraco cannot pin the blame for its predicament on Forest and thus lacks Article III standing to pursue its declaratory claims against Forest.

This case therefore presents an ideal opportunity to clarify this Court's traceability jurisprudence and to correct the Federal Circuit's erroneous and overly simplistic holding that "but for" causation is the beginning and the end of that inquiry. Intervention is critical in this area to remedy the lower courts' deep and abiding confusion and preserve Article III's core limits on the exercise of federal jurisdiction.

II. The Federal Circuit Erred By Holding That A Declaratory-Judgment Plaintiff Has Standing Where The Plaintiff's Complaint Does Not Challenge The Legality Of The Particular Action Or Conduct Alleged To Have Caused The Plaintiff's Asserted Injury.

Even if naked but-for causation were sufficient to demonstrate traceability, the Federal Circuit further erred by holding that a declaratory-judgment plaintiff has standing where the plaintiff's complaint does not challenge the legality of the particular action or conduct alleged to be responsible for the plaintiff's asserted injury. Indeed, this Court repeatedly has held that Article III standing requires the plaintiff's suit to present precisely such a challenge. *See, e.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000) ("[T]o satisfy Article III's standing requirements, a plaintiff must show [that its] injury is fairly traceable to *the challenged action of the defendant*.") (emphasis added) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998) ("[T]here must be causation—a fairly traceable connection between the plaintiff's injury and *the complained-of conduct of the defendant*.") (emphasis added); *Allen v. Wright*, 468 U.S. 737, 751 (1984) ("A plaintiff must allege personal injury fairly traceable to *the defendant's allegedly unlawful conduct . . .*.") (emphasis added); *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99 (1979) (plaintiff must "show that he personally has suffered some actual or threatened injury as a result of *the putatively illegal conduct of the defendant*") (emphasis added).

The requirement that standing requires the plaintiff to trace its injury to conduct actually challenged in the litigation makes perfect sense. If the Constitution permitted would-be plaintiffs to obtain a legal ruling by suing a defendant whose conduct has allegedly made them worse off — regardless of whether that conduct is the subject of the ruling sought or even alleged to be *unlawful* — then the federal courts effectively would possess general jurisdiction to issue advisory opinions that do not address concrete legal disputes between the plaintiff and defendant, and that are not even predicated on allegations of legal wrong.

That, however, is precisely what the Federal Circuit has permitted in this case. In holding that Caraco has standing to pursue a declaratory judgment that its proposed generic EO products would not infringe the '941 patent, the Federal Circuit reasoned that "Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete." Pet. App. 27a; *see also id.* 26a (asserting that "Caraco's injury is traceable to Forest" because "if Forest had not listed its ... patents in the FDA's Orange Book..., then [the statute] would not independently delay Caraco's ANDA from being approved") (capitalization omitted).

But Caraco's lawsuit does not complain about Forest's decision to list the '941 patent in the Orange Book at all — much less seek a declaratory judgment that Forest's decision to list the '941 patent in the Orange Book was unlawful. Instead, as the appellate court recognized, Caraco's suit against

Forest merely seeks a declaratory judgment that its proposed generic EO products would not infringe the '941 patent if those products were manufactured or marketed. *Id.* 17a ("Caraco filed a separate action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the Hatch-Waxman [Act], 21 U.S.C. § 355(j)(5)(C), seeking a declaratory judgment that the drug described in its ANDA does not infringe Forest's '941 patent."); *id.* 28a n.10 ("Caraco has not sought a judgment of invalidity in this case.").

However, the question of whether Caraco's EO product infringes the '941 patent — the only issue as to which Caraco seeks a federal court determination — is purely hypothetical in this case because Forest has validly and enforceably promised never to assert the '941 patent against that product. And the conduct to which Caraco traces its asserted Article III injury-in-fact, is not, and cannot be, the subject of a legal claim in any event. Under the Hatch-Waxman Act, brand manufacturers *must* submit for Orange-Book listing "any patent which claims the drug for which the [brand manufacturer sought FDA approval] and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed ... engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). Thus, even if one unlicensed company's generic product would not infringe a listed patent (as Caraco's product allegedly would not in this case), the brand-name drug's manufacturer properly may list that patent in the Orange Book so long as the patent covers (or "claims") the brand-name drug and its owner reasonably could assert infringement claims against some other unlicensed generic

applicant. Indeed, the law *requires* the brand manufacturer to do so.

The distinction between claims of non-infringement, on one hand, and claims that a brand manufacturer improperly listed a given patent in the Orange Book, on the other, is particularly sharp in this case. The '941 patent claims a narrowly defined particle size of EO, which is the active ingredient in Forest's brand-name product (Lexapro®). Wholly apart from the question presented by Caraco's declaratory judgment action — *i.e.*, whether Caraco's proposed generic product does or does not contain EO particles of the size covered by the '941 patent — no one has ever suggested that Lexapro® does *not* contain EO particles of the size claimed by the '941 patent or that Forest could not reasonably assert that patent against an unlicensed applicant whose proposed generic product *does* contain EO particles of the size claimed in the '941 patent.

Regardless of whether Caraco's injury somehow can be traced the Forest's patent-listing decision — and as set forth above, that is far from clear — Forest's legitimate decision to list the '941 patent in the Orange Book is not itself "the challenged action," *Friends of the Earth*, 528 U.S. at 180, or "complained-of conduct" in Caraco's suit, *Steel Co.*, 523 U.S. at 103, and thus cannot give Caraco Article III standing to pursue this case.

To be sure, nothing would preclude the federal courts from exercising jurisdiction over this action if Caraco actually were challenging Forest's patent-listing decision. Indeed, numerous courts have recognized that unlawful patent listings can give rise to liability under the Sherman Act, and thus have

authorized generic applicants to bring lawsuits asserting such claims in federal court. *See, e.g.*, *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004) (recognizing an antitrust cause of action for sham Orange Book listings); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 n.8 (4th Cir. 2002) (same); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (same). Nor would anything preclude Caraco from bringing a "civil action for patent certainty" under 21 U.S.C. § 355(j)(5)(B)(iv) if it genuinely faced patent *un*certainty. But this is not such a case; Caraco seeks only a declaration of *non-infringement*, and that claim does not remotely depend on whether Forest's Orange Book listing was proper in the first instance.

The Federal Circuit thus erred in holding that the federal courts have jurisdiction over declaratory judgment actions like Caraco's, and this Court should grant the writ.

CONCLUSION

For the foregoing reasons, the petition should be granted and the Federal Circuit's judgment reversed.

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IN THE

Supreme Court of the United States

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS, LTD.,
and H. LUNDBECK A/S,

Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE PFIZER INC. IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*[1]

Pfizer Inc. ("Pfizer") is one of the world's largest innovator pharmaceutical companies, dedicated to developing and commercializing safe, effective, and affordable medicines. Pfizer invests heavily in research and product development to bring to market new products that address major unmet health care needs. Due to the significance of the Federal Circuit Court of Appeals' decision to innovator companies such as Pfizer and Forest, and to the pharmaceutical industry as a whole, Pfizer submits its *amicus curiae* brief in support of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S's (collectively, "Forest") Petition for a Writ of Certiorari (the "Petition").

Acquiring and enforcing patents is critical to the mission of innovator pharmaceutical companies like Pfizer. Pfizer frequently participates in patent litigation against generic pharmaceutical manufacturers pursuant to the legal framework established by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). Indeed, Pfizer has been a party in cases in which the Court of Appeals for the Federal Circuit addressed the issue before the Court: declaratory judgment jurisdiction in the Hatch-

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, or their counsel, made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief. The parties have been given at least 10 days notice of the intention to file this *amicus* brief.

Waxman context. See, e.g., Teva Pharms. USA, Inc. v. Pfizer Inc., 395 F.3d 1324 (Fed. Cir. 2005); Apotex Inc. v. Pfizer Inc., No. 04-1463, 125 Fed. Appx. 987, 2005 WL 821393 (Fed. Cir. April 11, 2005). Pfizer has a continued interest in ensuring that the Federal Circuit correctly and consistently applies the test for declaratory judgment jurisdiction in the Hatch-Waxman context. In particular, Pfizer has an interest in ensuring that it is not required to risk its patents in litigation every time a generic drug manufacturer files an Abbreviated New Drug Application ("ANDA"). In the absence of an actual controversy with the generic company, and where Pfizer has no business reason for filing suit for infringement, it should not have to engage in litigation.

Pfizer submits its *amicus* brief based on its experience with the relevant laws. Pursuant to this Court's Rules, *amicus* briefs are appropriate when the party submitting the brief "brings to the attention of the Court relevant matter not already brought to its attention by the parties." SUP. CT. R. 37; see also Neonatology Assocs., P.A. v. Comm'r, 293 F.3d 128, 130-31 (3rd. Cir. 2002) (Alito, J.). Pfizer's brief provides, inter alia, relevant statutory background and legislative history that gives meaningful context to the Hatch-Waxman Act amendments addressed in the Federal Circuit's majority opinion and will aid in the Court's consideration of Forest's Petition.

SUMMARY OF ARGUMENT

The Court should review and reverse the Federal Circuit's ruling that Forest's covenant not to sue Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), a generic drug manufacturer, for patent infringement did not eliminate the patent controversy between the parties (the "Opinion"). The Opinion raises important constitutional and jurisdictional concerns regarding declaratory patent actions brought under 28 U.S.C. § 2201, and conflicts with longstanding and recent Federal Circuit precedent. It also contravenes the statutory language and legislative history of the Hatch-Waxman laws by creating a new cause of action for generic manufacturers, and undermines Congress's express incentive to ANDA filers that are the first to challenge patents covering an innovator drug product. Further, the Opinion undermines the Article III "case or controversy" requirement and obligates Forest to litigate, and the trial court to resolve, a hypothetical patent conflict that will result in the improper issuance of an advisory opinion that could have no effect on Forest's rights and duties. The Federal Circuit has, in effect, rewritten the Hatch-Waxman Act in a manner exceeding its judicial authority.

Courts have long held that a covenant not to sue for infringement eliminates any controversy between a patentee and a potential infringer. The Federal Circuit's decision departs from this precedent and predicates declaratory judgment jurisdiction upon non-party IVAX Pharmaceuticals, Inc.'s ("IVAX") eligibility for generic exclusivity under the Hatch-Waxman Act. The Federal Circuit determined that first-ANDA-filer IVAX's exclusivity period was an "injury" to declaratory plaintiff and later-ANDA-filer Caraco. The Federal Circuit then "traced" that injury to Forest's listing of the patent-in-suit in the publication *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," notwithstanding that Forest was required to list its patent under 21 U.S.C. § 355(b)(1).

In finding jurisdiction for Caraco's declaratory judgment action, the Federal Circuit primarily relied on the "Civil Action to Obtain Patent Certainty," codified at 21 U.S.C. § 355(j)(5)(C). Congress enacted the Civil Action to Obtain Patent Certainty, among other amendments to the Hatch-Waxman laws, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (the "Medicare Amendments"). The Federal Circuit failed to consider the relevant legislative history of the Medicare Amendments, addressing in isolation only the comments of Senator Kennedy concerning the Civil Action to Obtain Patent Certainty. Senator Kennedy did not sponsor the Medicare Amendments, and in fact voted against them. As outlined in Pfizer's *amicus* brief, those comments, considered in context, and the balance of the relevant legislative history, mandate the dismissal of Caraco's declaratory judgment action.

In enacting the Medicare Amendments, Congress actually considered, but rejected, the creation of automatic declaratory jurisdiction for generic drug manufacturers. Congress instead indicated that courts should apply the same standard for subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, in the Hatch-Waxman context as in any other patent case. The Opinion is therefore at odds with the legislative history of the relevant statute which, unlike Senator Kennedy's comments about the Civil Action to Obtain Patent Certainty, is germane to the jurisdictional question in this case. The Opinion also conflicts with recent Federal Circuit precedent holding that a covenant not to sue did moot the controversy between the patentee and the potential generic infringer, and that a patentee's compliance with a statutory requirement, like listing patents in the Orange Book, could not create declaratory judgment jurisdiction.

Given the substantial jurisdictional and constitutional concerns raised by the Opinion, and because the Federal

Circuit failed to apply the same jurisdictional test as it would in any other patent case, the Court should, in consideration of the relevant legislative history and case law outlined in Pfizer's brief, grant Forest's Petition.

ARGUMENT

I. THE FEDERAL CIRCUIT'S ATTEMPT TO CREATE JURISDICTION FOR ANDA FILERS CONTRAVENES EXPRESS CONGRESSIONAL INTENT

The Court of Appeals for the Federal Circuit must apply the law as enacted and according to Congressional intent. Griffith v. Oceanic Contractors, Inc., 458 U.S. 564, 576 (1982); Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 123-24 (1980). The Federal Circuit disregarded that obligation and overstepped its judicial authority in this case. As both the statutory text and legislative history of the relevant Hatch-Waxman provisions make clear, Congress did not create a unique cause of action for ANDA filers. Moreover, Congress expressly rejected automatic jurisdiction for ANDA filers and stated its expectation that courts would apply the established jurisdictional test for patent declaratory actions. Because the Federal Circuit failed to apply the Hatch-Waxman law according to clear Congressional intent, review and reversal is appropriate.

A. Congress Did Not Create a New Cause of Action for ANDA Filers

Caraco brought its action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the provision of the Medicare Amendments establishing the Civil Action to Obtain Patent Certainty, 21 U.S.C. § 355(j)(5)(C). The Federal Circuit primarily relied on the latter provision in finding jurisdiction for Caraco's declaratory judgment action. The statutory language and legislative history of the Civil Action to Obtain Patent Certainty make clear, however, that ANDA filers like Caraco must satisfy the same

jurisdictional requirements under 28 U.S.C. § 2201 as any other patent challenger.

Congress enacted the Civil Action to Obtain Patent Certainty, among other changes to the Hatch-Waxman laws, as part of the Medicare Amendments. Long before the Medicare Amendments, the Hatch-Waxman Act itself allowed an ANDA filer to bring an action under 28 U.S.C. § 2201 with respect to an Orange Book-listed patent, under certain conditions and provided that the standards for declaratory judgment jurisdiction were met. See 21 U.S.C. § 355(j)(5)(B)(iii) (1984). With the Medicare Amendments, Congress imposed additional conditions on an ANDA filer's ability to bring a declaratory action under 28 U.S.C. § 2201.[2] See 21 U.S.C. § 355(j)(5)(C) (2003). Both the pre- and post-Medicare Amendments Hatch-Waxman provisions make clear that, even if the ANDA filer meets the Act's requirements, any declaratory judgment action it might file must be brought under 28 U.S.C. § 2201.

The Medicare Amendments also amended the patent laws, creating subsection (e)(5) of 35 U.S.C. § 271, entitled "Infringement of patent." The Federal Circuit relied on this new subsection for "extended jurisdiction over Civil Actions to Obtain Patent Certainty." The subsection makes no

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[2] These additional conditions include that an ANDA filer that alleges non-infringement of the listed patent must now provide an "offer of confidential access" to its ANDA. 21 USC §§ 355(j)(5)(C)(i)(I)(cc), (III). Congress also clarified that an ANDA filer could not bring a declaratory judgment action if it had been sued by the patentee or NDA-holder within the 45-day period. 21 USC § 355(j)(5)(C)(i)(I)(bb). The original Hatch-Waxman Act stated only that a declaratory judgment action could not be brought within the 45-day period. See 21 U.S.C. § 355(j)(5)(B)(iii) (1984).

reference to "Civil Actions to Obtain Patent Certainty," however, as a basis for declaratory jurisdiction or otherwise. See 35 U.S.C. § 271(e)(5). In fact, it states that ANDA filers are required to bring and maintain their declaratory judgment actions under 28 U.S.C. § 2201: courts in ANDA cases "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (emphasis added).

The legislative history of the Medicare Amendments also expressly states that Congress did not intend to create a new cause of action or to expand the existing authority for ANDA filers under 28 U.S.C. § 2201. Senator Hatch, co-sponsor of the original Hatch-Waxman Act, stated with respect to the Medicare Amendments:

> I also want to make explicit, the implicit – that nothing in this new language pertaining to pharmaceutical patent-related declaratory judgments creates a new cause of action separate from the existing authority under title 28.

149 CONG. REC. S15,567 (daily ed. Nov. 22, 2003). Declaratory judgment actions under section 2201 maintain the jurisdictional requirement of an underlying patent dispute between the patentee and the patent challenger.

As is clear from the statutory text and legislative history, section 2201 of title 28 is the sole jurisdictional basis for a declaratory judgment action by an ANDA filer. Section 2201 itself provides no support for expanded jurisdiction in ANDA cases, but actually emphasizes that declaratory judgment jurisdiction in such cases is subject to specific limitations, including the restrictions discussed above and set forth in the new Civil Action to Obtain Patent Certainty provision, 21 U.S.C. § 355(j)(5)(C). Section 2201(b) reads as follows:

> (b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act.

28 U.S.C. § 2201(b) (emphasis added).[3] Contrary to the Federal Circuit's finding, therefore, there is simply no statutory basis for finding declaratory judgment jurisdiction in the Hatch-Waxman context when none would exist outside of it.

B. Congress Has Expressly Rejected Automatic Jurisdiction

By endorsing this basis of jurisdiction, the Opinion essentially creates automatic jurisdiction for all generic patent challengers. If an innovator company's irrevocable covenant not to sue does not eliminate a patent controversy, a later-filing generic manufacturer could bring a declaratory action solely to obtain a judgment enabling it under the Hatch-Waxman scheme to attack the 180-day exclusivity of a first-filer, a non-party to the suit. In effect, the innovator could be forced to risk its patents in litigation solely to further the declaratory plaintiff's competition with its generic-manufacturer rivals, not to resolve an actual controversy involving the innovator. In enacting the Medicare Amendments, however, Congress contemplated the jurisdictional test that should be applied in ANDA cases. Congress considered but rejected "automatic" declaratory judgment jurisdiction, instead providing that courts should apply the same test as in any declaratory patent action, finding jurisdiction where appropriate.

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[3] The new Civil Action to Obtain Patent Certainty provision with respect to ANDAs is set forth in subsection 505(j)(5)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(C)).

The Senate proposed creating automatic jurisdiction in Hatch-Waxman cases. Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. § 702(c) (2003). The Senate's proposal failed to become law, however, because of concerns about the constitutionality of legislating the existence of subject matter jurisdiction. Article III of the Constitution limits the judicial power of the United States to the resolution of "cases" and "controversies." U.S. CONST. art. III, § 2, cl. 1; Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982). "No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases and controversies." Raines v. Byrd, 521 U.S. 811, 818 (1997) (citation omitted). Declaratory actions are appropriate only when there is an actual controversy. See, e.g., Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 239-241 (1937).

The Senate recognized that creating automatic declaratory judgment jurisdiction by statute could contravene Article III of the Constitution:

> At our June 17th hearing, DOJ did not present the Judiciary Committee with its final opinion on the matter but Mr. Sheldon Bradshaw, Deputy Assistant Attorney General, Office of Legal Counsel, noted, "that the actual case of [sic] controversy requirement is constitutionally compelled rather than statutorily required. And as a result, Congress can't simply create a case or controversy by statute but the plaintiffs must establish the constitutional requirement for bringing the case."... I have requested the Department of Justice for its formal views on this language.

149 CONG. REC. S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch) (emphasis added). After the Department of

Justice determined that the Senate declaratory judgment provision was unconstitutional, 149 CONG. REC. S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch), Congress "correct[ed] the constitutional flaw in the Senate-passed bill." 149 CONG. REC. S16,104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch). Consequently, the bill that became new 35 U.S.C. § 271(e)(5) did not contain the automatic jurisdiction language of the earlier bill.

Instead, in the Conference Report, and elsewhere in the legislative record, Congress indicated that it expected courts to apply the same jurisdictional test in the Hatch-Waxman context as in any other patent case. H.R. REP. NO. 108-391, at 836 (2003) (Conf. Rep.) (stating that the conferees did not intend for courts to modify their application of the jurisdictional requirements under Article III, and citing to a non-Hatch Waxman case, Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466 (Fed. Cir. 1997)). A conference report is the primary authority for interpreting statutes based on legislative history. Demby v. Schweiker, 671 F.2d 507, 510 (D.C. Cir. 1981) (MacKinnon, Circuit Judge).

C. The Federal Circuit Failed to Consider the Relevant Legislative History in Proper Context

The Federal Circuit considered only certain remarks of Senator Kennedy in concluding that "delay" caused by a generic competitor's 180-day exclusivity period was the type of injury that the Civil Action to Obtain Patent Certainty was meant to redress. Senator Kennedy did not sponsor the Medicare Amendments, and in fact voted against the Amendments. See 149 CONG. REC. S15,915 (daily ed. Nov. 25, 2003), so his comments are of little use in determining Congress's intent. Moreover, Senator Kennedy's comments, considered in the context of the Conference Report, indicate that the 180-day exclusivity period did not create the type of "delay" in FDA approval of ANDAs that concerned Congress.

As stated in the Conference Report:

> The conferees expect courts to find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies.

H.R. REP. NO. 108-391, at 836 (2003) (Conf. Rep.). This statement provides context for the remarks of Senator Kennedy which directly addressed the significance of covenants not to sue (and which the Federal Circuit wrongly dismissed in a footnote):

> We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003). The Federal Circuit discounted these comments of Senator Kennedy because they were made at a time when the Federal Circuit applied solely the "reasonable-apprehension" test for determining whether a declaratory judgment action satisfied Article III. However, Senator Kennedy's remarks refer to "case or controversy," not a "reasonable apprehension of suit." As the Conference Report makes clear, in enacting the Civil Action to Obtain Patent Certainty provision, Congress was principally concerned with <u>delayed</u> litigation between the innovator company and the ANDA filer. A covenant not to sue eliminates that concern.

II. EXERCISE OF JURISDICTION IN THIS CASE WOULD UNDERMINE ARTICLE III OF THE CONSTITUTION AND YIELD AN UNCONSTITUTIONAL ADVISORY OPINION

The Opinion disregards constitutional limitations on the judiciary. Article III courts are prohibited from issuing

advisory opinions absent a constitutionally-required "case or controversy." See U.S. CONST. art. III, § 2, cl. 1; Preiser v. Newkirk, 422 U.S. 395, 401-02 (1975). A declaratory judgment action must pose "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts" in order for jurisdiction to lie. Preiser, 422 U.S at 401. Forest's covenant not to sue eliminated any controversy between Forest and Caraco. The Opinion thus compels an impermissible advisory opinion from the trial court which would be premised on a hypothetical: that Forest could assert its patent against Caraco. The resolution of this hypothetical situation, should Forest prevail, could result in relief that would have no legal effect on Forest's rights and duties.

Article III courts "do not sit to decide hypothetical issues or to give advisory opinions about issues as to which there are not adverse parties." Princeton Univ. v. Schmid, 455 U.S. 100, 102 (1982) (per curiam). A "hypothetical threat" of adverse action is insufficient to satisfy Article III in declaratory judgment actions – a court may address a case "only when the interests of litigants require the use of . . . judicial authority for their protection against actual interference." United Public Workers v. Mitchell, 330 U.S. 75, 90 (1947); see also Preiser, 422 U.S. at 402 (requiring controversy "between parties having adverse legal interests, of sufficient immediacy and reality") (emphasis in original). Nor can a court exercise declaratory judgment jurisdiction based on what "would have been" absent intervening circumstances. Ashcroft v. Mattis, 431 U.S. 171, 172 (1977).

Caraco requires no intervention to protect against Forest's "actual interference." Indeed, Forest's covenant bars it from interfering with Caraco's attempts to market a generic product. The Opinion nonetheless relies on Forest's patent ownership, and the listing of that patent in the Orange

Book, to create a hypothetical conflict between Forest and Caraco. The Opinion requires an Article III court to assess whether Caraco would infringe Forest's patent absent Forest's covenant. Whether Caraco infringes Forest's patent while Forest cannot sue for infringement is no more justiciable, however, than assessing whether a party would have been liable absent a particular defense, or whether regulations would have been permissible had they not been amended. See Princeton, 455 U.S. at 102-03; Aschcroft, 431 U.S. at 172. Deciding such an "abstract, hypothetical, [and] contingent question[ ]" is plainly unconstitutional. Alabama State Fed'n of Labor v. McAdory, 325 U.S. 450, 461 (1945).

Moreover, federal courts may not "decide questions that cannot affect the rights of litigants in the case before them" See, e.g., Preiser, 422 U.S. at 401; North Carolina v. Rice, 404 U.S. 244, 246 (1971). Indeed, the touchstone of a "case or controversy" is "the settling of some dispute which affects the behavior of the defendant towards the plaintiff." Lawyer v. Dep't of Justice, 521 U.S. 567, 579-80 (1997) (quoting Hewitt v. Helms, 482 U.S. 755, 761 (1987)) (emphasis in original). This Court has recognized that actions taken by the parties outside of court may render the court unable to affect a party's rights and obligations with a judgment, thus rendering any subsequent judicial opinion advisory in nature. Preiser, 422 U.S. at 401-04 (dismissing because act giving rise to alleged harm had been unilaterally rectified by defendant); Princeton, 455 U.S. at 102 (dismissing because defendant amended regulations at issue in opinion below).

Because of the covenant, a favorable decision for Forest in a hypothetical patent controversy with Caraco could not impact Forest's rights as against Caraco. Even if Forest prevailed in the underlying infringement lawsuit, it could not enforce its patent rights against Caraco, a result which would have no practical effect upon Forest's rights or behavior. Such a decision is an unconstitutional advisory opinion.

III. THE OPINION CONFLICTS WITH OTHER FEDERAL CIRCUIT DECISIONS

This Court has recognized that, in light of the Federal Circuit's nationwide appellate jurisdiction in patent cases, conflicts in the rulings of the Federal Circuit may warrant granting certiorari. See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (noting that divisions within Federal Circuit warrant Supreme Court review); Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 89 (1993) (noting that certiorari was warranted in Federal Circuit patent case because uniformity of patent law "is a matter of special importance to the entire Nation"); see also, e.g., Dickinson v. Petroleum Conversion Corp., 338 U.S. 507, 508 (1950) (granting certiorari "because of [an] intracircuit conflict"); Maggio v. Zeitz, 333 U.S. 56, 59 (1948) (addressing "conflicting views" within Second Circuit on subject of fraudulent bankruptcy); John Hancock Mutual Life Ins. Co. v. Bartels, 308 U.S. 180, 181 (1939) (granting certiorari because of conflict in rulings of Fifth Circuit).

The Opinion illustrates two points of conflict within the Federal Circuit: (1) whether a covenant not to sue moots any controversy between a patentee and the potential infringer, and (2) whether a patentee's compliance with a statutory requirement can create a justiciable Article III controversy between it and an alleged infringer.

A. Covenants Not To Sue

The Federal Circuit's overwhelming precedent establishes that a covenant not to sue moots any controversy between a patentee and a potential infringer. Even following the demise of the two-part "reasonable apprehension" test as the sole basis of jurisdiction, the Federal Circuit has held that an irrevocable covenant not to sue moots any controversy between a patentee and a potential infringer. Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1347-48 (Fed. Cir. 2007).

In the Opinion, the Federal Circuit did not purport to overrule its precedent concerning covenants not to sue, nor could it, Nippon Steel Corp. v. U.S., 458 F.3d 1345, 1351 n.3 (Fed. Cir. 2006). Instead, the Federal Circuit held that "Forest's covenant not to sue did not eliminate the controversy" between the parties in the context of Hatch-Waxman because of the competitive advantage sought by Caraco concerning the 180-day exclusivity period. (Op. at 2.) Five months later, however, a different panel of the Federal Circuit reached the opposite conclusion in Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008). In Janssen, the Federal Circuit held that a covenant not to sue did moot the controversy, and did not permit the later-filing declaratory plaintiff to use a declaratory judgment action against the innovator to prematurely trigger the first-filer's exclusivity period.

In Janssen, the innovator company, Janssen, listed three patents in the Orange Book with respect to its drug Risperdal®. Id. at 1357. First-filer Teva Pharmaceuticals USA, Inc. ("Teva") challenged two of those patents, making it eligible for 180-days of generic exclusivity. Id. at 1358. Janssen declined to sue on the two challenged patents, rendering Teva's ANDA approvable upon the expiration of the third, unchallenged patent (the "'663 patent"). Id.

Apotex, the declaratory plaintiff in Janssen, filed a later ANDA for Risperdal®. Apotex stipulated to the infringement and validity of the '663 patent and sought declaratory judgments with respect to the other two patents. Id. Janssen granted Apotex a covenant not to sue on those two patents and moved to dismiss Apotex's counterclaims. Id. at 1358-59. Apotex opposed that motion, arguing that the inability to launch its product immediately after the '663 patent expired due to Teva's 180-day exclusivity period created a controversy between Janssen and Apotex. Id. at 1359.

The district court granted Janssen's motion and dismissed the case. The Federal Circuit affirmed, holding that Apotex's inability to launch its product at the same time as Teva – immediately upon expiration of the '663 patent – did not create a justiciable controversy between Janssen and Apotex. The delay of Apotex's launch, the court held instead, was "a result envisioned by the Hatch-Waxman Act." Id. at 1361. The court attempted to distinguish its earlier Opinion in this case: "[U]nlike Caraco, Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent – it stipulated to the validity of the '663 patent." Id.

Notwithstanding the Federal Circuit's attempt to distinguish the Opinion, the Janssen and Caraco decisions plainly conflict. In both cases, the generic manufacturer sought a declaratory judgment in order to trigger a third party's exclusivity period. Id. at 1360 ("[I]f Apotex is successful on its declaratory judgment action, Teva's exclusivity period will be triggered . . . ."), 1361 ("Caraco wanted to be able to challenge both patents and if successful, this would trigger Ivax's 180-day exclusivity period . . . ."). In both cases, the patentee granted the generic manufacturer a covenant not to sue. The Janssen court found that there was no justiciable controversy regarding the first filer's exclusivity period, while the Caraco court reached the opposite conclusion.

The Hatch-Waxman Act is complex, and Hatch-Waxman cases frequently involve multiple patents and include and affect numerous generic defendants. The tenuous factual distinction drawn by the Janssen court will undoubtedly produce conflicting decisions in the future, both within the Federal Circuit and in the district courts. While this Court has acknowledged that decisions regarding jurisdiction over declaratory judgment cases may be fact-sensitive, the complexity of Hatch-Waxman cases requires a clear delineation of the effects of covenants not to sue on Article

III jurisdiction. Without such delineation, future panels of the Federal Circuit will determine declaratory judgment jurisdiction based on the panel's view of the fairness in each case of allowing the second-filer to attempt to trigger, prematurely, the non-party first-filer's exclusivity period. As discussed below, the Federal Circuit cannot substitute its own policy concerning generic exclusivity for that of Congress.

B. Tracing Injury to Compliance with a Statutory Requirement

The Federal Circuit found Article III jurisdiction based on Caraco's alleged injury of "restrain[t] from the free exploitation of non-infringing goods," (Op. at 19-20), tracing that purported injury to Forest's listing of its patents in the Orange Book. (Id. at 21-22.) As Section II of Forest's Petition discusses in detail, tracing Caraco's purported injury to Forest offends Article III of the Constitution. Under the Hatch-Waxman Act, a brand manufacturer must identify to the FDA all patents covering a drug "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1). Forest's compliance with this statute cannot render any alleged resulting injury attributable to Forest.

The Federal Circuit's holding that Caraco's injury is "fairly traceable" to Forest is inconsistent with its holding in Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329 (Fed. Cir. 2008), decided only four months after the Opinion. In Prasco, the patentee had marked its product as being covered by four patents pursuant to 35 U.S.C. § 287. Id. at 1334. The declaratory plaintiff sought declaratory judgments that its competing product did not infringe those four patents. Id. Section 287 provides that patentees may give notice to the public by marking their products, and further provides that if a patentee fails to so mark, "no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and

continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice." 35 U.S.C. § 287(a). The Federal Circuit determined that the patentee's marking of its product pursuant to 35 U.S.C. § 287(a) "[was] not a circumstance which supports finding an imminent threat of harm sufficient to create an actual controversy." Id. at 1334, 1340-41.

Just as the patentee in Prasco marked its product with its patents pursuant to 35 U.S.C. § 287, thereby alerting potential competitors to the possibility of an infringement suit, Forest listed its patents covering Lexapro® in the Orange Book pursuant to 21 U.S.C. § 355(b)(1). Both statutes are intended to provide notice of patents to potential infringers. Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc., 482 F.3d 1317, 1319 (Fed. Cir. 2007) (noting that patents disclosed pursuant to § 355(b)(1) are "published in the 'Orange Book,' a register that provides notice of patents covering name brand drugs"); State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1073 (Fed. Cir. 2003) ("Section 287 of the Patent Act provides that patentees shall give notice of infringement by marking 'any patented article' . . . ."). But while the Prasco court found that the patentee's decision to mark its product was "irrelevant," the Federal Circuit found that Caraco's injury was in fact traceable to Forest's "decision" to list its patents in the Orange Book.

As Section II of the Petition details, Forest could not have omitted its patents from the Orange Book without suffering severe civil and criminal penalties. In contrast, in Prasco, the patentee could have chosen not to mark its product, the only potential consequence of which would be a limited damages recovery if it was successful in an infringement suit. 35 U.S.C. § 287(a). Therefore, Forest's listing of its patents in the Orange Book should be less persuasive of an intent to enforce its patents than the permissive marking of products under section 287. The Federal Circuit's conflicting decisions in the Opinion and Prasco warrant this Court's

review to clarify when, if ever, disclosing patents to potential competitors pursuant to a federal statute can satisfy a jurisdictional requirement under Article III.

IV. THE FEDERAL CIRCUIT CANNOT SUBSTITUTE ITS OWN POLICY CONCERNING THE 180-DAY EXCLUSIVITY PERIOD FOR THAT OF CONGRESS

The Opinion contradicts Congress's objectives in implementing the generic exclusivity award, and creates grounds for a new possible exclusivity trigger not endorsed by Congress: a declaratory action by a secondary ANDA filer brought solely to spoil the first-filer's exclusivity. No statutory basis exists for such an action, and such a result necessarily undermines the incentive to first-filers that invest significant resources to challenge or litigate the validity and/or infringement of a patent. The Opinion also generates unnecessary litigation by essentially forcing an innovator company to litigate its patents against every single ANDA challenger, even those it covenants not to sue.

With the Hatch-Waxman Act, Congress chose to reward the first ANDA filer to include a paragraph IV certification as an incentive to encourage generic manufacturers to risk challenging innovator companies' pharmaceutical patents. See 21 U.S.C. § 355(j)(5)(B)(iv) (1984). Congress reconsidered eligibility for generic exclusivity during the enactment of the Medicare Amendments.[4] Senator Hatch advocated for a "successful defense requirement" for generic exclusivity, under which Congress would reward the first

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[4] Although the amendments to the 180-day generic exclusivity period effected by the Medicare Amendments are largely inapplicable here, Medicare Amendments, §1102(b), 117 Stat. at 2460, they are indicative of Congress's intent with respect to generic exclusivity.

ANDA filer to obtain a favorable court decision on the listed patent. 149 CONG. REC. S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch). Congress rejected this approach, again indicating its intention that the first filer to include a paragraph IV certification should be eligible for the reward.[5]

IVAX, as the first generic manufacturer to file an ANDA for Lexapro® and challenge Forest's '941 patent, is eligible for the 180-day exclusivity award conferred by Congress. The Federal Circuit determined that Caraco should be allowed to maintain its declaratory judgment action solely to attempt to "activate" first-filer IVAX's Congressionally-mandated exclusivity period. This bias towards prematurely triggering the first ANDA filer's exclusivity, in essence favoring subsequent generic manufacturers which often file years later and have not expended the same resources or undertaken the same risks as the first filer, is contrary to Congress's policy with respect to the 180-day exclusivity period. Congress's balancing of the equities between the first generic challenger and subsequent generic challengers is crystallized in the 180-day exclusivity period, the starting point of which is critical to the first filer. Congress has clearly set forth the possible triggers for that 180-day exclusivity period in the Hatch-Waxman laws. The Federal Circuit may not substitute its own policy concerning the 180-day exclusivity period for that of Congress by creating a new exclusivity trigger. Only Congress can amend the Hatch-Waxman laws to address any perceived inequities with the 180-day generic exclusivity period; courts "must apply the statutory scheme as written." Teva Pharms. USA, Inc., 395 F.3d at 1338; see also Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 124 (D.C. Cir. 2006).

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[5] After the Medicare Amendments, the first ANDA filer to challenge any of the NDA holder's listed patents is eligible for generic exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (2003).

For various business reasons, including the desire to limit widespread litigation against ANDA filers, innovator pharmaceutical companies, such as Pfizer, may grant covenants not to sue in certain circumstances to avoid the expense of multiplicative patent litigation. The Federal Circuit's holding prevents an innovator company from choosing not to assert its patent, and essentially forces it to engage in expensive and time-consuming patent litigation against all generic challengers on every single listed patent solely so that the later-filing generic challenger can attempt to spoil the first filer's exclusivity. In some cases, there may be more than twenty different generic challengers to multiple patents with respect to a single innovator drug product. This result is not only unjust to both innovator and generic companies, but contrary to clear Congressional intent concerning the relevant Hatch-Waxman provisions. The Opinion is ripe for review and reversal.

CONCLUSION

For the foregoing reasons, this Court should grant Forest's petition for a writ of certiorari.

Respectfully submitted,

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No. 08-624

IN THE

Supreme Court of the United States

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS, LTD.,
AND H. LUNDBECK A/S,
Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Respondent.

On Petition for Writ of Certiorari To the United States Court of Appeals For the Federal Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether a generic drug company possesses Article III standing to sue for a declaratory judgment that it has not infringed a patent relating to an FDA-approved drug, where the patentee has granted it an irrevocable covenant not to sue for infringement.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

WLF believes strongly that maintenance of a limited government requires courts to respect limitations on their jurisdiction and to avoid reaching out to adjudicate matters not involving a justiciable case or controversy. WLF has regularly participated in federal court proceedings in which the scope of the judicial power is at issue. *See, e.g., Friends of Earth v. Laidlaw Environmental Services (TOC),* 528 U.S. 167 (2000); *Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83 (1998). WLF filed a brief in this case in the Federal Circuit, in support of the petition for panel rehearing and rehearing *en banc*.

WLF is concerned that the Federal Circuit's decision, if allowed to stand, would expand federal court jurisdiction w ell beyond the limitations imposed by

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondent with notice of its intent to file this brief.

Article III of the Constitution, which limits jurisdiction to "Cases" or "Controversies." WLF does not believe that federal courts should be in the business of rendering advisory opinions of the sort Respondent Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is seeking in this case. In the absence of any case or controversy, Caraco's appropriate recourse is to take its case to Congress and to request revision of the rules governing the grant of a 180-day exclusivity period for the first filer of an ANDA – not to complain to a court about the unfairness of those rules.

WLF has no direct interest – financial or otherwise – in the outcome of this case. It is filing its brief for the sole purpose of urging the Court to establish firm rules designed to ensure that federal courts operate exclusively within the confines of their Article III jurisdiction. WLF is filing its brief with the consent of all parties; letters of consent have been lodged with the Court.

STATEMENT OF THE CASE

Petitioners Forest Laboratories, Inc., *et al.* (collectively, "Forest"), developed (and for a number of years have been marketing) Lexapro®, a drug approved by the Food and Drug Administration (FDA) for treatment of depression and generalized anxiety disorder. Prior to initiation of this lawsuit, Forest owned two patents that covered Lexapro or its use, and it listed those patents in FDA's Orange Book.

Because of Lexapro's commercial success, numerous generic drug companies are interested in marketing a generic form of Lexapro. But federal law

prohibits a generic drug company from doing so until such time as FDA approves the company's Abbreviated New Drug Application (ANDA) for its generic version of the drug. It is the absence of an approved ANDA, not Forest's patents, that ultimately is preventing Caraco from marketing a generic version of Lexapro.

In seeking to promote the Nation's health care delivery system, Congress has recognized two important goals that are in considerable tension with one another. On the one hand, Congress seeks to provide an economic incentive for new product development by granting pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies the opportunity to reap substantial rewards in those few instances in which their research and development bear fruit. It does so by affording pioneering drug manufacturers a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. On the other hand, once that appropriate period of exclusivity has expired, Congress has determined that consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

There is an inherent tension between these two goals – rewarding research and development while lowering the cost of drugs through competition. Congress attempted to strike a balance between those competing interests when, in 1984, it adopted the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* Pub. L. 98-417, 98 Stat. 1585 (1984), codified at 21

U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Act benefitted generic manufacturers by creating the ANDA procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. 21 U.S.C. § 355(j). The Act benefitted pioneering manufacturers by granting patent-term extensions under certain circumstances. 35 U.S.C. §§ 156 & 21 U.S.C. § 355a(c)(2).

The Act also included a provision designed to encourage challenges to potentially invalid drug patents – it provided rewards to the first generic drug manufacturer to take on the burden of challenging a drug patent. The Act provided that, subject to certain limitations, the first ANDA filer was entitled to a 180-day exclusivity period following the launch of its product pursuant to an approved ANDA, during which no other generic company's ANDA would be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

The Act also set forth procedures for resolving patent disputes between pioneering and generic manufacturers. Those procedures are set forth in § 505(j) of the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 355(j). The FDCA provides that FDA is to maintain a list of FDA-approved drugs and to include on that list (known as the "Orange Book") any patent information respecting those drugs. 21 U.S.C. § 355(j)(7)(A).[2] If a generic manufacturer seeks to

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[2] Supplying such patent information to FDA is not optional. Any pioneering drug company that applies to FDA to market a new drug *must* include in its application detailed information regarding all patents that claim the drug or a method of using the drug. 21

market a generic version of an approved drug for which a patent is claimed in the Orange Book (and wants to do so before the expiration of a listed patent), the manufacturer must include in its ANDA a certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[3] Congress has decreed that the filing of a Paragraph IV certification injures a patent holder by infringing his property rights in the patent, and has authorized patent holders to file an infringement suit against the Paragraph IV filer. 35 U.S.C. §§ 271(e)(2)(A) & 281. The Act also permits the filer of a Paragraph IV certification, under certain circumstances, to file a civil action for a declaratory judgment of noninfringement and/or invalidity. 21 U.S.C. § 355(j)(5)(C).

Caraco notified Forest of its ANDA filing in May 2006, many years after the first ANDA for generic Lexapro was filed by Ivax Pharmaceuticals, Inc. Ivax's ANDA included Paragraph IV certifications with respect to the two patents listed in the Orange Book for Lexapro (the '712 patent and the '941 patent). In subsequent patent infringement litigation initiated by Forest with respect to the '712 patent, the federal courts upheld the patent and held that it was infringed by Ivax's filing. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007). Forest did not sue Ivax over the '941 patent. Because the '712 patent does not expire until

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U.S.C. §§ 355(b)(1) & (2), 355(c)(2).

[3] Such a certification is often referred to as a "Paragraph IV certification."

2012, FDA will not approve the sale of a generic version of Lexapro until after that date – unless another generic manufacturer successfully challenges the '712 patent in court.

As noted above, by virtue of its status as the first Paragraph IV filer with respect to both the '712 patent and the '941 patent, Ivax is entitled to a 180-day exclusivity period during which the numerous ANDAs filed by other generic drug companies will not be approved. 21 U.S.C. § 355(j)(5)(B)(iv). In all likelihood, the 180-day period will be deemed to commence on the day that Ivax begins selling its generic drug (presumably in 2012, when the '712 patent expires). Caraco filed this suit in hopes that it can trigger an earlier start to the 180-day exclusivity period and thereby accelerate the launch of its own generic version of the drug.

Caraco's ANDA for Lexapro, filed in May 2006, included a Paragraph IV certification for both the '712 patent and the '941 patent. Forest responded by suing Caraco for infringement of the '712 patent; that suit is scheduled for trial in April 2009. Forest did not sue Caraco for infringement of the '941 patent, nor does Caraco allege that Forest ever threatened such a suit.

Caraco nonetheless filed this declaratory judgment action against Forest, seeking a declaration that the drug described in its ANDA did not infringe Forest's '941 patent. Forest thereafter granted Caraco an irrevocable covenant not to sue for infringement of

the '941 patent. Pet. App. 19a.[4] Based on that covenant, the district court granted Forest's motion to dismiss the case, finding that it lacked Article III jurisdiction in light of the absence of any controversy between the parties regarding Caraco's noninfringement of the '941 patent. *Id.* 49a-79a.

Splitting 2-1, a Federal Circuit panel reversed the district court's jurisdictional ruling and remanded the case. *Id.* 1a-43a. The majority held that Caraco's declaratory judgment action "present[ed] a justiciable Article III controversy," based on its determinations that Caraco possessed standing to sue, that the controversy was ripe for review, and that the granting of a covenant not to sue did not render the case moot. *Id.* 23a.

In its analysis of standing, the appeals court held that Caraco is suffering injury-in-fact because, the court concluded, the listing of the '941 patent in the Orange Book was an obstacle to Caraco's effort to win FDA approval of its ANDA. *Id.* 24a. The court explained that but for the '941 patent listing, Caraco would be permitted to market its drug 180 days following expiration of the '712 patent (or 180 days after a judgment striking down the '712 patent, which ever

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[4] In its filings in the courts below, Caraco repeatedly observed that Forest did not explicitly concede that the Caraco ANDA did not infringe the '941 patent. WLF fails to understand the relevance of that observation, particularly given Caraco's failure to challenge the validity of the '941 patent. For all practical purposes, a patentee's covenant that it will not sue X for infringement of its patent is equivalent to a statement by the patentee that X has not infringed its patent.

comes first), rather than being forced to wait until 180 days after Ivax voluntarily decides to begin marketing its drug -- and that that impediment to marketing constituted the requisite injury-in-fact. *Id.* 24a-25a.[5] The court held that Caraco's injury was "fairly traceable" to Forest's complained-of conduct in that Forest's Orange Book listings were a "but-for" cause of the injury: but for those listings, Caraco's ANDA would readily be approved. *Id.* 26a. The court also held that Caraco's injury is redressible by this lawsuit: granting a declaratory judgment would "clear the path" to FDA approval of Caraco's ANDA, because at that point the only obstacles to approval would be a Caraco victory in its pending judicial challenge to the '712 patent followed by the elapse of 180 days. *Id.* 28a.

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[5] Caraco argued in the appeals court that by virtue of Ivax's loss of the patent infringement action suit filed by Forest, Ivax has forfeited its 180-day exclusivity period with respect to the '712 patent, and thus that if Caraco wins this suit it will be permitted to begin marketing on the very day that the '712 patent expires (or the day that it is held invalid). However, the Federal Circuit has repeatedly made clear that it rejects that argument. Rather, the Federal Circuit has stated, a generic drug manufacturer's 180-day exclusivity period with respect to a Paragraph IV certification remains in effect even if its challenge to the listed patent is rejected. *See, e.g., id.* at 14a ("[B]ecause Ivax was the first Paragraph IV ANDA filer with respect to both the '712 and '941 patents, a subsequent Paragraph IV ANDA filer can only activate Ivax's exclusivity period via the court-judgment trigger by obtaining a judgment that both the '712 and '941 patents are invalid or not infringed."). In other words, even if Caraco manages to activate the court-judgment trigger with respect to both patents, it must still wait 180 days before it can begin marketing its drug. In the absence of a cross-petition from Caraco on this issue, the Federal Circuit's interpretation of the rules governing the 180-day exclusivity period are controlling.

The appeals court also held that Caraco's declaratory judgment action was ripe for review, *id.* 31a-34a, and that it had not been rendered moot by Forest's grant of an irrevocable covenant not to sue Caraco for infringement of the '941 patent. *Id.* 34a-36a. The court said that Forest's covenant did not eliminate Caraco's injury: the potential delay in FDA approval of its ANDA caused by the existence of Forest's Orange Book listings.

REASONS FOR GRANTING THE PETITION

The petition raises issues of exceptional importance. By limiting the federal judicial power to the resolution of actual "Cases" and "Controversies," Article III of the Constitution plays an important role in maintaining a balanced allocation of power among the three branches of the federal government. The case-or-controversy requirement ensures that the federal courts limit the exercise of their powers to those occasions on which parties with adverse legal interests are engaged in a concrete and substantial dispute, and do not render decrees that opine on hypothetical facts or adjudicate "disputes" that are not actually disputed by the parties. Yet, the Federal Circuit has now determined that it possesses jurisdiction to issue just such decrees in a category of patent cases that affects a large number of extremely valuable drug patents. Its stated rationale for doing so is a desire to ensure that generic drugs can be more easily marketed – thereby potentially reducing consumers' prescription drug costs.

Review is urgently needed to ensure that the Federal Circuit, along with all other federal courts, confine their exercise of jurisdiction to cases and controversies falling within their Article III powers.

The Federal Circuit determined that a generic drug company has standing to file an action seeking a declaratory judgment that its proposed marketing plans do not infringe an existing patent, even though the patentee never gave the company any indication that it intended to sue for infringement and, indeed, ultimately provided the company with an irrevocable covenant that it would *never* sue for infringement. When there is not, nor has there ever been, a disagreement between two parties regarding the scope of a patent, it defies all understanding to suggest that there exists a justiciable controversy regarding the patent. The mere fact that if a judgment is rendered, one party may gain an advantage in some other proceeding – in this instance, Caraco's application for ANDA approval – does not alter the fact that Article III deprives federal courts of authority to exercise jurisdiction over matters that are not genuinely in dispute. It is up to Congress – not the Federal Circuit – to determine if changes are warranted in FDA drug-approval rules for the purpose of further streamlining the ANDA process and thereby bringing about further reductions in retail drug prices.

The Federal Circuit shrugged off Forest's objections to having to defend a lawsuit in which no issues are genuinely in dispute, by stating that Forest could avoid the costs of litigation it if would merely "submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent." Pet. App. 28a n.11. But the consent of the parties does not relieve federal courts of their independent obligation to ensure that they are operating within the constitutionally prescribed limits to their powers. *Arizonans for Official English v. Arizona*, 520 U.S. 43, 73 (1997). While some patentees may agree to a consent

judgment rather than going to the expense of contesting jurisdiction in a suit seeking a declaration of noninfringement that no one disputes, that does not excuse a federal court's decision to exercise jurisdiction in a matter so clearly outside its Article III powers.

The appeals court's determination that Caraco has suffered injury-in-fact sufficient to establish standing cannot withstand analysis. In past instances in which the Court has upheld jurisdiction over an action seeking a declaratory judgment that a patent is either invalid or not infringed, it has done so based on findings that the mere existence of the patent has in some way harmed the plaintiff. Either the patentee has created reasonable apprehension that the plaintiff will be sued for infringement, or the patent causes the plaintiff to forebear from activity that it would engage in but for the likelihood that doing so would lead to a potentially ruinous patent infringement suit. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S. Ct. 764 (2007).

In this case, Caraco does not allege that it has been harmed by the existence of the '941 patent or even that the '941 patent is invalid. Rather, Caraco asserts that it has been injured due to potential delays by FDA in approving its ANDA to market generic Lexapro, and that those potential delays are greater than they might otherwise have been had Forest not caused the '941 patent to be listed in the Orange Book. Given that Caraco does not allege that it has been injured by the existence of the '941 patent, it lacks standing to bring a

declaratory judgment action with respect to the patent.[6]

There is no reason to delay review of the issue to allow it to percolate in the federal appellate courts. Because all patent cases come through the Federal Circuit, all such cases will be decided under the overly expansive understanding of Article III jurisdiction adopted in this case. Moreover, as the appeals court recognized, Pet. App. 10a n.4, its analysis of Article III jurisdictional limits applies both to cases (as here) where 180-day exclusivity issues are governed by the pre-2003 statutory scheme and to cases in which such issues are governed by the new statutory scheme adopted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003)("MMA"). *See* 21 U.S.C. § 355(j)(5)(D). Accordingly, unless review is granted in this case, the Federal Circuit is likely to continue to exercise jurisdiction in patent cases well beyond the scope of its Article III authority.

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[6] Caraco's alleged injury would most likely be sufficient to establish standing to sue FDA for its decision to list the '941 patent in the Orange Book. But that is not the cause of action that Caraco has filed. Moreover, the Federal Circuit has made clear that federal law does not provide a cause of action against either FDA or patentees for improper Orange Book listings. *See, e.g., Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), *cert. denied*, 537 U.S. 941 (2002).

I. REVIEW IS WARRANTED TO ENSURE THAT THE FEDERAL CIRCUIT CONFINES ITS EXERCISE OF JURISDICTION TO CASES AND CONTROVERSIES FALLING WITHIN ITS ARTICLE III POWERS

Caraco seeks a declaratory judgment that it has not infringed the '941 patent. Although the Declaratory Judgment Act, 28 U.S.C. § 2201, permits parties to file suits in which (as here) the only relief sought is declaratory in nature, it did not (and could not) relax Article III's command that an actual case or controversy exist before federal courts may adjudicate a question. U.S. Const., Art. III, § 2. *See Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 272-73 (1941).[7] The Act merely provides a different procedure for bringing an actual case or controversy before a federal court; it does not purport to expand federal court jurisdiction. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1941). Review is warranted because the court below established a rule that will result in the Federal Circuit exercising jurisdiction over a broad category of cases in which no actual case or controversy exists.

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[7] The Act provides in relevant part:

> In a case of actual controversy within its jurisdiction . . . any Court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). As the Court has explained, § 2201(a)'s "actual controversy within its jurisdiction" language refers to the types of "Cases" and "Controversies" that are justiciable under Article III. *MedImmune*, 127 S. Ct. at 771

In *MedImmune*, the Court recently reiterated the traditional formulation regarding the minimum prerequisites necessary to meet the case-or-controversy requirement:

> Basically, the question in each case is whether the facts alleged, under all the circumstances, show th at there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

MedImmune, 127 S. Ct. at 771. Caraco does not meet those prerequisites: there is *no* controversy (and certainly not a "substantial" one) between the parties regarding the '941 patent, they have no adverse legal interests, and any controversy lacks immediacy given the absence of any ongoing relationship between them. Forest reinforced that point by providing Caraco with an unconditional covenant not to sue, thereby eliminating any possible controversy and rendering moot all claims related to the '941 patent.

A. Caraco Lacks Article III Standing

As the Federal Circuit recognized, Pet. App. 23a, an action is not justiciable under Article III where the Plaintiff lacks standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 550, 560 (1992). The "irreducible constitutional minimum" of standing contains three elements: the plaintiff must (1) have suffered a "concrete," "particularized," and "actual or imminent" injury-in-fact that (2) is "fairly traceable to the challenged action of the defendant" and that (3) is likely to be redressed by a favorable decision. *Id.* at 560-61.

In finding that those three elements were met in this case, the Federal Circuit adopted an analytic approach that conflicts sharply with this Court's approach to standing issues.

The appeals court held that Caraco has suffered injury-in-fact directly traceable to Forest's conduct because Forest's decision to supply information to FDA regarding the '941 patent may, through a complex chain of events, delay the date on which Caraco eventually obtains FDA approval of its ANDA. Pet. App. 24a-27a. But the court failed to explain why that alleged injury bears any relation to the claims in this lawsuit – which challenges the '941 patent itself, not the decision to post it in the Orange Book.

As the Court has explained:

> [S]tanding is gauged by the specific common-law, statutory, or constitutional claims that a party presents. "Typically, . . . the standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication *of the particular claims asserted*."

Primate Protection League v. Administrators of Tulane Educ. Fund, 500 U.S. 72, 77 (1991) (quoting *Allen v. Wright*, 468 U.S. 737, 752 (1984)) (emphasis in original). The particular claim asserted in this case is that Caraco's proposed drug does not infringe the '941 patent; in other words, the lawsuit focuses on the existence and scope of the patent. But the injury alleged by Caraco (and accepted by the Federal Circuit as sufficient to establish standing) has nothing to do with

the existence and scope of the '941 patent. Rather, the Federal Circuit held that Caraco's injury consists of the fact that Forest took steps that resulted in FDA listing the '941 patent in the Orange Book. Because that alleged injury has at most a highly tangential relationship to the existe nce and scope of the '941 patent, it is insufficient to constitute the injury-in-fact necessary to provide Caraco with standing.

The Court's decision in *Blum v. Yaretsky*, 457 U.S. 991 (1982), is illustrative. The plaintiffs in *Blum* represented a class of Medicaid patients who were challenging procedures employed by hospital officials in transferring patients both to higher and lower levels of care. The Court held that although the plaintiffs could demonstrate injury-in-fact with respect to procedures governing transfers to lower levels of care, such injury was insufficient to provide them with the injury-in-fact necessary to establish standing to challenge procedures governing transfers to *higher* levels of care. *Blum*, 457 U.S. at 1001. The Court explained that merely because one action taken by a defendant has injured a plaintiff does not mean that the plaintiff possesses standing to file suit against the defendant for the defendant's other, largely unrelated actions that have not injured the plaintiff. *Id.* at 999. Similarly, by supplying information to FDA regarding the '941 patent (an action required by the FDCA in connection with all new drug applications) and thereby ensuring that the '941 patent would be listed in the Orange Book, Forest arguably injured Caraco by making it marginally more difficult for Caraco to obtain FDA approval of its ANDA. But any such injury is wholly unrelated to this lawsuit, which challenges the scope of the '941 patent, not its listing in the Orange Book. To establish standing to file

this declaratory judgment action, Caraco would need to demonstrate that the existence of the '941 patent was injuring it in some way; Caraco has made no such demonstration.

B. *MedImmune* Provides No Support for the Appeals Court's Standing Determination

The Federal Circuit cited this Court's *MedImmune* decision as its justification for expanding the circuit's prior understanding regarding when a party has standing to file an action seeking a declaratory judgment that a patent is either invalid or not infringed. However, its understanding of *MedImmune* was fundamentally flawed. Prior to *MedImmune*, the Federal Circuit adhered to a "reasonable apprehension of suit" test, pursuant to which the case-or-controversy requirement was held to bar suits by a party seeking a declaratory judgment that a patent was invalid or not infringed, unless the party had a reasonable apprehension that the patent holder would sue him for infringement. *See, e.g., Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). *MedImmune* disapproved of the reasonable apprehension test, finding it inconsistent with Supreme Court precedent and an overly narrow interpretation of the case-or-controversy requirement. *MedImmune*, 127 S. Ct. at 774 n.11. But while *MedImmune* expanded the Federal Circuit's prior understanding of Article III jurisdiction, it did so in a manner wholly unrelated to the facts of this case.

MedImmune addressed a situation in which the party seeking declaratory relief is himself preventing the

complained-of injury from occurring. That is, only by complying with a demand from the defendant, a demand to which he objects, is the declaratory judgment plaintiff forestalling injury. The Supreme Court noted that under well-established case law, where the demand for compliance comes from the *government*, such a plaintiff need not refuse to comply with the demand – thereby exposing himself to government sanction – before being permitted to seek declaratory relief. *Id.* at 772.[8] The Court determined that the same rule should apply where the demand for compliance comes not from the government but from a private party, at least where the threatened sanction for noncompliance is quite severe: "The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80% of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III." *Id.* at 775. Thus, the *MedImmune* plaintiff was permitted to seek a declaratory judgment that it was not infringing a patent at the same time that it was forestalling a potentially devastating infringement action by paying royalties to the patent holder. *Id.* at 777. The issue was no less a "substantial controversy" between the parties simply because the plaintiff was paying tribute to the patent holder under protest. *Id.*

Caraco's situation does not even remotely resemble the facts in *MedImmune*. Caraco is not making any payments to Forest or taking any other

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[8] Thus, in *Steffel v. Thompson*, 415 U.S. 452 (1974), the Court "did not require the plaintiff to proceed to distribute handbills and risk actual prosecution before he could seek a declaratory judgment regarding the constitutionality of a state statute prohibiting such distribution." *Id.*

actions at Forest's behest. Caraco is refraining from marketing a generic form of Lexapro not because of any actions by Forest but because FDA has not approved its ANDA. Nor has Forest ever given Caraco any indication that it intended to sue for infringement of the '941 patents; to the contrary, Forest provided Caraco with an unconditional covenant *not* to sue. Moreover, Caraco is attempting to use a declaratory judgment action for the purpose warned against in *MedImmune*: it is seeking piecemeal adjudication of its claims, with the hope that a judgment here will benefit it in other proceedings. *Id.* at 771 n.7 ("[A] litigant may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying controversy.") (citing *Calderon v. Ashmus*, 523 U.S. 740 (1998)). In short, despite the Federal Circuit's reliance on *MedImmune*, nothing in that decision provides support for the appeals court's conclusion that Caraco meets the case-or-controversy requirement.

Caraco, as the party claiming declaratory judgment jurisdiction, bears the burden of establishing that such jurisdiction existed at the time it filed suit *and at all times thereafter*. *Steffel,* 415 U.S. at 459 n.10. Even if Caraco arguably possessed standing at the time it filed its complaint, that standing was eliminated once Forest provided its unconditional covenant not to sue – thereby eliminating any possible claim of injury arising by virtue of the '941 patent. From that point forward, any arguable claim possessed by Caraco with respect to the '941 patent was rendered moot. Caraco is asking the federal courts to reach a legal determination that Forest has pledged not to challenge: that Caraco's Paragraph IV certification did not violate Forest's rights under the

'941 patent. The federal courts lack Article III jurisdiction to issue such advisory opinions.

Finally, even if the injury allegedly suffered by Caraco (a potential delay in approval of its ANDA) could be deemed traceable to the mere existence of the '941 patent, that relationship is far too attenuated to establish standing. *Regardless* how this suit is resolved, the most likely date on which Caraco will obtain FDA approval of its ANDA is 180 days following expiration of the '712 patent in 2012. While a judgment for Caraco in this case would prevent that date from being delayed, the Federal Circuit conceded that there is no evidence indicating that such a delay is likely.[9] For Caraco to obtain FDA approval of its ANDA prior to 2012, it will need to prevail in court on its claim that the '712 patent is invalid – and there is no basis for assuming it "likely" that Caraco will prevail given that Ivax's identical effort to overturn the '712 was unsuccessful. Accordingly, Caraco cannot meet the "redressability" requirement for standing, because it cannot establish that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561. While Caraco *might* be helped by a favorable decision in this case, it is just as likely that a favorable decision will have *no* effect on the date on which Caraco's ANDA ultimately receives FDA approval.

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[9] A decision by Ivax to delay marketing even after expiration of the '712 patent in 2012 could delay the triggering of Ivax's 180-day exclusivity period. But a judgment for Caraco in this case with respect to the '941 patent combined with the expiration of the '712 patent would ensure that Ivax's exclusivity period would expire after the elapse of 180 days following the patent's expiration in 2012.

II. THE DECISION BELOW SUBSTANTIALLY REVISES THE BALANCE STRUCK BY CONGRESS AND AFFECTS A SUBSTANTIAL NUMBER OF CASES

Review is also warranted because the decision below will likely have a substantial impact on pharmaceutical innovation. Petitioner has explained that impact in significant detail, Pet. 31-35; rather than repeating that explanation fully here, WLF will focus on a few major points.

First, as noted above at 3-4, the Hatch-Waxman Act was intended to establish a careful balance between rewarding innovation (by providing market exclusivity to those who develop new therapies) and reducing consumer costs (by encouraging competition after an appropriate period of exclusivity has expired). By abandoning traditional standing rules in an effort to encourage more competition at any earlier stage of product development, the Federal Circuit is threatening to upset that balance. Review is warranted to ensure that any changes in the Hatch-Waxman balance are effected by Congress, not the courts.

Second, the Federal Circuit's re-writing of the Hatch-Waxman compromise harms not only pioneering drug companies but also generic drug companies who assume the substantial costs of being the first to challenge a drug patent by filing the first Paragraph IV certification with respect to the patent. Congress created the 180-day exclusivity period for first filers to encourage generic drug companies to assume the costs of challenging patents of dubious validity. Review is warranted because the decision below undermines those

intended financial incentives by allowing suits, as here, whose principal purpose is to limit or destroy a first-filer's 180-day exclusivity period.

Third, as the Petition indicates, the questions presented herein are present in scores of pending drug patent cases and thus are of tremendous importance to the pharmaceutical industry and our Nation's health care delivery system. Moreover, the 2003 changes to the law are unlikely to decrease the frequency with which the issue arises in the future. The MMA revised the law by eliminating the court-judgment trigger provisions of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). But as the Federal Circuit noted, its jurisdictional analysis is as applicable to the new law as it is to the pre-2003 law. Pet. App. 10a n.4.[10] In both instances, the decision below would grant standing to a generic drug manufacturer who filed an action seeking a declaratory judgment that its Paragraph IV certification did not infringe a patent listed in the Orange Book – regardless whether the patentee had ever suggested that it might bring an infringement action. Under the decision below, standing would exist so long as it is *possible* that a judgment for the plaintiff could speed the approval of the plaintiff's ANDA – a possibility that will always exist under both the old and new statutory schemes. Accordingly, review is warranted in light of the large number of cases that are affected and will continue to be

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[10] Under the law as revised by the MMA, a judgment finding that a drug patent is either invalid or not infringed by a Paragraph IV certification effectively requires the first filer to begin marketing immediately. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). That provision serves the same function as § 355(j)(5)(B)(iv)(II) (2000), the court-judgment trigger provision of the pre-2003 statute.

affected by the decision below.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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